EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-01

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-11-005	01/01/2011 To 12/31/2012 Base Option Period Number 1	RWQC

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	3.1,3.4 - 3.6

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 01/01/2011 To 12/31/2012

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (Max 2): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 01/01/2011 To 12/31/2012		0
This Action:		3,700
Total:		3,700

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Sharon Nappier (Signature) (Date)		Branch/Mail Code: Phone Number: 202-566-0740 FAX Number:
Project Officer Name: Shirley Harrison (Signature) (Date)		Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Other Agency Official Name: Shirley Harrison (Signature) (Date)		Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Contracting Official Name: Donna Reinhart (Signature) (Date)		Branch/Mail Code: Phone Number: 513-487-2114 FAX Number:

PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-11-005
WORK ASSIGNMENT #1-01

Title: Activities to support the development of revised Recreational Water Quality Criteria (RWQC)

Work Assignment Manager: Sharon Nappier (Mail Code 4304T)
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Period of Performance: January 1, 2012 through December 31, 2012

LOE: 3780 hours

Contractor SOW: 3.1, 3.4, 3.5, 3.6

****Note: No CBI data will be needed in the course of this work assignment.**

Background:
The mission of the United States Environmental Protection Agency's Office of Water (OW) under the Safe Drinking Water Act and the Clean Water Act (CWA) includes protecting the public health from adverse affects of microbial pollutants in waters for swimming.

A key component in the CWA framework for protecting and restoring waters for swimming is State adoption of Water Quality Standards (WQS) to protect swimmers from illnesses associated with "microbes" in the water. One of EPA's key roles is to recommend Recreational Water Quality Criteria (RWQC), under Section 304(a) of the CWA, for adoption by the States. These EPA recommended criteria have been historically based on fecal matter in the water; in the 1960's the Federal government recommended a certain level of fecal coliform as the recreational criteria and in 1986 EPA recommended certain levels of enterococci and *E. coli* as its new recreational criteria. These organisms do not generally cause human illness themselves; rather, they

are merely indicators of fecal contamination and therefore indicators of the potential presence of human pathogenic organisms.

It has been over 20 years since EPA last issued recreational criteria. Science - particularly molecular biology, virology and analytical chemistry - have advanced significantly during this time. EPA believes that new scientific and technical advances need to be considered, if feasible, in the development of new or revised 304(a) criteria. To this end, EPA has been conducting research and assessing relevant scientific and technical information to provide the scientific foundation for the development of new or revised criteria. The enactment of the BEACH Act provided EPA with an opportunity to conduct new studies and provided additional impetus to issue new or revised criteria for coastal recreational waters (specifically, for Great Lakes and coastal marine waters) to replace or amend the 1986 EPA recommended criteria. EPA believes that the new or revised criteria must be scientifically sound, implementable for broad CWA purposes, and provide for improved public health protection over the 1986 criteria.

Quality Assurance: Tasks 2-5 in this work assignment require the use of secondary data and require a QAPP specific to the activities being conducted. Consistent with the Agency's quality assurance (QA) requirements, the contractor must supplement the quality assurance project plan (QAPP), required under Task 1 of this work assignment, to assure the quality of the secondary data or any other types of data used under this work assignment. The QAPP must be approved by the EPA before activities using secondary data begin.

The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1 and should follow the attachment titled, QAPP Requirements for projects using secondary data.

Statement of Work: The scope of work in this assignment will fall under the following task areas:

Task 1 – Workplan and Monthly Progress Reports

The Contractor shall develop a work plan to address all tasks in this work assignment. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than $100.00 shall be itemized in detail. The Contractor shall provide their job number with all invoices to facilitate their expediency.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must

include a table with the invoice LOE and costs' broken out by the tasks in this WA.

Task 2 – Support ongoing Action Development Process Workgroup (ADP WG) efforts in the development of the Recreational Water Quality Criteria (**RWQC)**

The Contractor shall assist in the ongoing efforts of the ADP WG. The Contractor shall attend weekly on-site ADP WG meetings, provide note-taking support, and submit meeting notes to the EPA WAM within two (2) business days of each ADP WG meeting. Additionally, the Contractor shall prepare meeting materials that may include, but are not limited to, presentations, briefing materials, hand-outs, and overviews.

Travel: Local travel is anticipated for this Task. No contractor travel outside of the Washington, D.C. metro area is required.

Task 3 - Support for developing and editing the RWQC document and other related efforts

Task 3.1 *Develop RWQC document*

This is a continuation of previous efforts to assist in the development of the RWQC document. This task will be an ongoing effort for the period of performance of this work assignment and a series of Drafts are expected. The most recent Draft RWQC document will be provided to the Contractor by the EPA WAM. The Contractor shall schedule a phone meeting with EPA WAM, within five (5) days of the receipt of the WA to discuss the schedule needs for the RWQC document.

Task 3.2 *Prepare briefing materials and other supporting documents pertaining to the RWQC document*

Briefing materials and other supporting documents will be needed during Final Agency Review, public comment, and during other parts of the Criteria development process. Briefing materials and supporting documents may include the development of secondary analyses to help support the development of the 2012 RWQC. The Contractor shall aid the in the development of any materials or presentations for these purposes.

Task 3.3 *Respond to Draft RWQC comments*

The Draft RWQC will undergo several types of reviews before it is finalized. These reviews include, but are not limited to, FAR, OMB review, public comment period, and interagency review. The Contractor shall respond to all comments from all reviews and provide an updated RWQC document to the EPA WAM.

While there are multiple ways to deal with the comments, EPA will likely choose either to use ICF's proprietary Comment Works or an Excel add-in. The decision regarding which of the two programs that EPA will choose for handling comments will be provided through technical direction.

Task 3.4 *Prepare and submit Final RWQC document*

The Contractor shall prepare and submit a Final Recreational Water Quality Criteria (RWQC) document. This document will need to be 508 Compliant and formatted as directed by the EPA WAM.

Travel: No contractor travel outside of the Washington, D.C. metro area is anticipated for this task.

Task 4 – Gathering and preparing materials for the EPA docket

A "docket" is a collection of documents made available by an agency for public viewing often associated with an opportunity for public comment. EPA's dockets consist of materials used in developing a particular rulemaking or other action issued by the Agency.

Task 4.1. *Prepare comprehensive list of materials needed in the docket*

The Contractor shall help identify materials that need to be placed in the EPA docket. Docket materials may include, but are not limited to, publications, data, and meeting notes.

Task 4.2. *Gather and prepare materials needed in the docket*

Once the docket materials list has been reviewed by the EPA WAM, the Contractor shall help gather and prepare all the materials that need to be placed in the EPA docket. Again, docket materials may include, but are not limited to, publications, data, and meeting notes.

Travel: No contractor travel outside of the Washington, D.C. metro area is required is anticipated for this task.

Task 5 - General Project Support

The contractor shall, based on technical direction given by the EPA WAM, provide support in preparing interim project update and other materials for internal and external audiences. These may include, but are not limited to, short briefing documents and PowerPoint presentations. The contractors may also be directed to participate in and/or conduct briefings. A weekly update call with the EPA WAM will be required for this work assignment, as needed.

Some meetings may require Contractor support and/or attendance for note-taking, presentations, and meeting preparation materials. Additionally, ODCs have been added for travel for up to two (2) trips. Details on travel dates and locations will be provided by the EPA WAM through technical direction, as further information becomes available.

Travel: Travel may be needed as deemed necessary by the EPA WAM. No contractor travel outside of the Washington, D.C. metro area is required.

SCHEDULE AND DELIVERABLES:

Task No.	DELIVERABLE	Schedule
1	1.1 Work Plan	Within 10 business days of receipt of WA
2	2.0 ADP WG notes and other materials.	TBD
3	3.1 Draft RWQC	TBD
3	3.2 Supporting documents	TBD
	3.3 Draft RWQC - Response to comments	Within 1 week of the Review
3	3.4 Final RWQC	TBD
4	4.1 Comprehensive list of materials for EPA docket	TBD
4	4.2 Compilation of materials for EPA docket	TBD
5	5.0 General Project Support	TBD

Knowledge and Skills Required: Contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this work assignment. The Contractor shall have practical experience in conducting microbial risk assessments and have advanced credentials in environmental microbiology. The Contractor shall be familiar with the use of fecal indicator organisms, microbiological analytical methods (including molecular techniques), water monitoring applications of epidemiological data, determination of human exposure to environmental contaminant sources, and gastrointestinal disease endpoints.

General Requirements of the Work Assignment and Schedule:

Due Dates: The Contractor shall provide due dates that are mutually acceptable with the EPA WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.
Delays: The Contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.
Draft Documents: The Contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. EPA WAM will provide comments on draft submissions prior to submission of final documents.
Final Documents: The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM.

Attachment 1

QAPP REQUIREMENTS FOR PROJECTS USING SECONDARY DATA

A secondary data project involves the gathering and/or use of existing environmental data for purposes other than those for which they were originally collected. These secondary data may be obtained from many sources, including literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. For these projects, a QAPP shall be prepared to include the requirements identified below. If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the secondary data. The following requirements should be addressed as applicable.

SECTION 1.0 PROJECT OBJECTIVES, ORGANIZATION, AND RESPONSIBILITIES

1.1 The purpose of study shall be clearly stated.
1.2 Project objectives shall be clearly stated.

1.3 The secondary data needed to satisfy the project objectives shall be identified. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable, shall be specified.

1.4 The planned approach for evaluating project objectives, including formulas, units, definitions of terms, data analysis (i.e. statistical analysis & any other types of data analysis), and assumptions/recommendations based on the data analysis, if applicable, shall be included.

1.5 Responsibilities of all project participants shall be identified, meaning that key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

SECTION 2.0 SOURCES OF SECONDARY DATA

2.1 The source(s) of the secondary data must be specified.
2.2 The rationale for selecting the source(s) identified shall be discussed.
2.3 The sources of the secondary data will be identified in any project deliverable.

SECTION 3.0 QUALITY OF SECONDARY DATA

3.1 Quality requirements of the secondary data must be specified. These requirements must be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if applicable. (If appropriate, a related QAPP containing this information can be referenced.)

3.2 The procedures for determining the quality of the secondary data shall be described.

3.3 If no quality requirements exist, this shall be stated in the QAPP. If no quality requirements exist or if the quality of the secondary data will not be evaluated by EPA, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the secondary data has not been evaluated by EPA for this specific application. The wording for the disclaimer shall be defined.

SECTION 4.0 DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION

4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.

4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.

4.3 The expected product document that will be prepared shall be specified (*e.g.*, journal article, final report, *etc.*).

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-01

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-11-005	01/01/2012 To 12/31/2012 Base Option Period Number 1	REC WQ Criteria

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	3.1, 3.4, 3.5, 3.6

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 01/01/2012 To 12/31/2012

Comments:
The purpose of this amendment is to authorize three additional trips so that the contractor can continue to support Task 5. There are enough funds in the WA to cover the additional trips at no additional cost. Details on travel dates and locations will be provided by the EPA WAM through technical direction. All other Tasks (Task 1 - Task 4) remain unchanged.

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 01/01/2012 To 12/31/2012 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee: — LOE:

Cumulative Approved: — Cost/Fee: — LOE:

Work Assignment Manager Name: Sharon Nappier (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-0740 FAX Number:
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Other Agency Official Name (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Cathy Basu (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2042 FAX Number:

PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-11-005
WORK ASSIGNMENT #1-01 Amd 1

Title: Activities to support the development of revised Recreational Water Quality Criteria (RWQC)

Work Assignment Manager: Sharon Nappier (Mail Code 4304T)
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Alternate WAM: John Ravenscroft (Mail Code 4304T)
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Period of Performance: Work Assignment issuance through December 31, 2012

Contractor SOW: 3.1, 3.4, 3.5, 3.6

Purpose of Amendment: The purpose of this work assignment amendment is to provide funding for up to three additional trips so the contractor can continue to support Task 5 (General Project Support). There are enough funds in the work assignment to cover additional trips at no cost. *Details on travel dates and locations will be provided by the EPA WAM through technical direction. All other Tasks (Task 1 – Task 4 remains the same, no change).*

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-03

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-11-005	01/01/2011 To 12/31/2012 Base Option Period Number 1	Incorporation of new Technolog

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	3.1,3.3, 3.4, 3.6

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 01/01/2012 To 12/31/2012

Comments:

☐ Superfund — **Accounting and Appropriations Data** — [X] Non-Superfund

SFO (Max 2): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Contract Period	Cost/Fee:	LOE:
	01/01/2011 To 12/31/2012		0
This Action:			490
Total:			490

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Shamima Akhter (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-0000 FAX Number:
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Other Agency Official Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Contracting Official Name: Donna Reinhart Donna Reinhart (Signature) 12/22/11 (Date)	Branch/Mail Code: Phone Number: 513-487-2114 FAX Number:

PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-11-005
WORK ASSIGNMENT # 1-03

Title: Incorporation of New Technologies to Support Criteria Development and Implementation

Work Assignment Manager:
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Period of Performance: January 1, 2012 through December 31, 2012

LOE: 490 hours

Contractor SOW: 3.1, 3.3, 3.4, 3.6

Background:
An important goal of the Clean Water Act is to protect and restore waters for swimming. A key component in the CWA framework for protecting and restoring waters for swimming in State adoption of water Quality Standards (WQS) to protect swimmers from illnesses associated with "microbes" in the water. One of the EPA's key roles is to recommend recreational water quality criteria (under section 304(a) of the CWA) for adoption by the States. These EPA recommended criteria have been historically based on fecal matter in the water; in the 1960's the Federal Government recommended certain levels of fecal coliform as the recreational criteria and in 1986 EPA recommended certain enterococci and E. coli as its new recreational criteria.

To provide increased protection to swimmers, and for development of Total Maximum Daily Loads (TMDLs), National Pollutant Discharge Elimination System (NPDES) permitting requirements and water quality listings, EPA is now poised to revise its decade old ambient water quality criteria. The old criteria developed in 1986 was mainly based on enumerations of Fecal Indicator Bacteria (FIB) using culture-based methods, some of which were originally developed over a century ago. The advent of scientific methods particularly in the molecular measurements of diverse microbial populations, analytical chemistry, virology, genomics

including metagenomics warrant reevaluations of the 1986 criteria development process. Research advances have revealed many of the shortcomings and uncertainties associated with the 1986 water quality criteria. EPA is committed to develop new recreational water quality criteria for all water body types by 2012. Before new criteria can be developed, it is imperative that EPA undertakes critical research, analyze existing research data so that a scientifically defensible and health protective criteria can be adopted.

New molecular assays with intrinsic characteristics of high sensitivity, specificity, and reproducibility allow more direct enumeration of potential pathogens in recreational water. For example, Immunomagnetic Separation / Adenosine Triphosphate (IMS/ATP), TaqMan Protein Assays, fluorescent-based microbe detection assays allow enumerations of indicator organisms very reliably. EPA is contemplating inclusion of Quanitiative Polymerase Chain reaction (qPCR) based enumerations of FIBs that can rapidly produce actionable results as opposed to the 24-48 hours that is now needed for culture based laboratory analysis. However, before new technologies can be incorporated in criteria development, numerous regulatory hurdles and related research needs must be met.

EPA anticipates a need to find out how we can use the data from the new technologies in the criteria development in the absence of epidemiological studies.

Quality Assurance: The tasks 2-3 in this performance work statement (PWS) require the use of primary/or secondary data and require a QAPP specific to the activities being conducted. Consistent with the Agency's quality assurance (QA) requirements, the contractor must supplement the quality assurance project plan (QAPP), required under Task 1 of this work assignment, to assure the quality of the secondary data and other data collected to be used under this work assignment. The QAPP must be approved by the EPA before activities using secondary data begin.

The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1 and should follow the attachment titled, QAPP Requirements for projects using secondary data.

Scope of Work: The scope of the work in this PWS will fall under the following task areas:

Task 1: Work plan and monthly progress reports

The contractor shall develop a detail work plan and cost estimate for each task outlined in this work assignment. The plan should contain, but not limited to, work-flowchart, elaborate schedule (task-wise), staffing plan and qualifications of proposed staff, budget for each task and level of effort (LOE). Prior to the submission of the work plan, the contractor shall consult with the EPA WAM via conference call to mitigate any potential issues that need clarifications. The contractor shall include information on plans to manage work and control contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than $100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency. The plan should be submitted no later than 15 working days after receiving this work assignment.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs' broken out by the tasks in this WA.

Task 1.1 Develop project specific QAPP

Tasks 2-3 and the new task 4 in this PWS require the use of primary and/or secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor must create a project specific quality assurance project plan (QAPP) to assure the quality of the secondary data and other data collected under task 4 to be used under this work assignment. There is an existing project specific QAPP from WA # B-03 that covers tasks 2-3. The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports and should follow Attachment 1 titled, QAPP Requirements for projects using secondary data.

The new task 4 in this work assignment requires an updated Quality Assurance Project Plan prior the commencement of work.

Task 2: Develop methodology for incorporation of new methods without epidemiological studies

In order to develop new robust Recreational Water Quality Criteria (RWQC), EPA is considering major technical methodologies that will allow future linkage to RWQC in the absence of additional epidemiological studies. EPA understands that the foremost requirements for RWQC include: RWQC should depend on the indicators that can be quantified reliably, robustly, and reproducibly; RWQC should protect individuals exposed to recreational waters; RWQC should protect children as they are more exposed and susceptible to pathogens; and RWQC should be scientifically defensible for application in a wide variety of geographical locations.

This PWS builds on previous work that is described in a report from a previous work assignment (WA 2-14, Task 2), under contract EP-C-07-036 titled *Options to Incorporate New Technologies and Methods into Recreational Water Quality Criteria without Additional Epidemiological Studies* (referred to as Report 2-14 hereafter).

The contractor shall further develop two approaches presented in Report 2-14, the risk level approach and the water quality approach. The below descriptions are from Report 2-14.

<u>Risk Level Approach - Use of Non-Standard Indicators with Associated Health Effects Relationships</u>

This approach, illustrated in Exhibit 1 below, involves relating two indicator-method combinations via selection of water quality standards from the two indicator-method combinations that relate to the same level of tolerable (acceptable/appropriate) risk. Although this approach allows for the use of established health effects relations for different indicators or from different epidemiological studies to be used within RWQC development, it requires that the health effects to which the indicators are related be the same and that the settings in which data

were collected be impacted by the same fecal pollution source. When epidemiological studies used to generate indicator density-health effects curves have different illness definitions (e.g., HCGI versus NEEAR GI), study designs, geographic regions, or time periods, analyses should be performed to convert the illness rates observed in the disparate studies to equivalent rates.

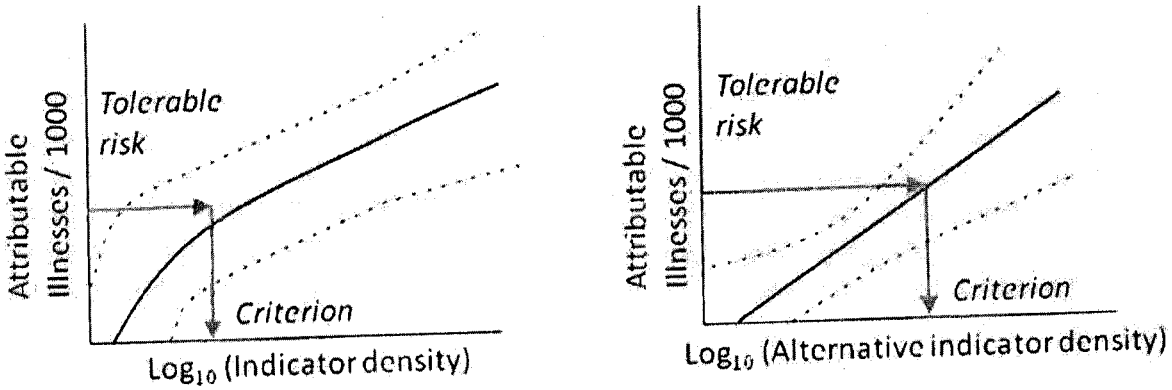

Exhibit 1. Illustration of an Alternative Indicator with Heath Effects Model Scenario. In this approach the alternate indicator has acceptable health effects data. The same risk as applied in the RWQC is applied to the new indicator and its health effects data.

Water Quality Based Approach - Indicators that are Directly Related to "Standard" Indicators that are in Turn Related to Epidemiology Data

If RWQC are based on a particular indicator-method combination (referred to here as the "standard" indicator), an alternative indicator-method combination may be related to the health effects association via linkage of the alternative indicator to the standard indicator. For example, epidemiological studies have established an association between *Enterococcus* density as determined by qPCR and the incidence of GI illness. This health effects curve may be used to establish a qPCR *Enterococcus* water quality criterion that is protective of health at a chosen level of risk. The question "what *Enterococcus* density via membrane filtration provides the same health protection as the qPCR criterion?" may be answered as follows. A model relating culturable *Enterococcus* density to qPCR-measured *Enterococcus* can be established, and uncertainty in the model and conditions for which the model is valid may be defined. The model can then be used to determine the *Enterococcus* culture density equivalent to the *Enterococcus* qPCR RWQC. This process is illustrated in Exhibit 2 below.

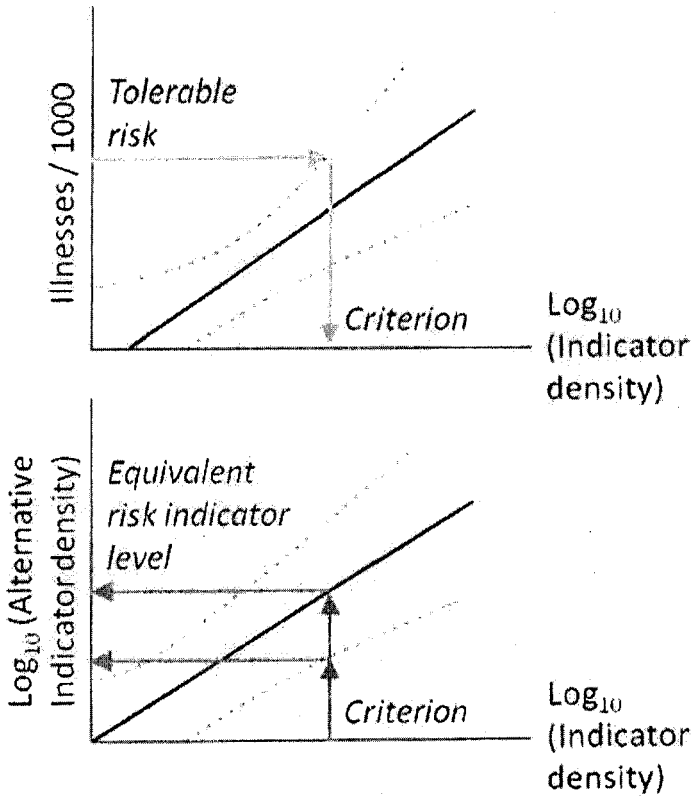

Exhibit 2. Linking to Health Effects Data via Equivalence of Water Quality Data

For this method to be viable, a robust, verifiable relationship must be established between the standard and alternative indicator(s). Establishing this relationship requires: (1) selection of a "gold standard" method against which alternative methods are compared; (2) rigorous demonstration of a relationship between the standard and alternative indicator entailing demonstration that results of assays of environmental samples of the two indicators are consistently related (e.g., when one rises, the other also rises), recoveries of the methods are within an acceptable range, and uncertainty and variability of the alternative method is not significantly greater than that of the gold standard; and (3) establishment of the conditions/settings for which the relationship between the standard and alternative indicator is valid.

EPA is interested in methods that may be incorporated for water quality assessment in the future as well as those that may be adopted in the near term, including those that can possibly be incorporated into water quality standards in the absence of epidemiological studies.

Identify methods and obtain datasets

To test the feasibility of the two approaches outlined above, sample datasets will be compared using the two different approaches. The contractor shall discuss with the EPA WAM the selection of appropriate datasets for the methods listed in report 2-14. Promising methods that were listed include qPCR, Propidium Monoazida (PMA-qPCR), Reverse Transcriptase

Polymerase Chain Reaction (RT-PCR), IMS¬ATP, Covalent (COV IMS-ATP), Transcriptase-mediated Amplification-Ribonucleic Acid (TMA-RNA), Nucleic Acid Sequence based Amplification (NASBA), microarray detection, and biosensors. The contractor shall include additional methods in the analysis if those methods have available datasets that allow comparison. The contractor shall not conduct literature searches to identify additional methods, but additional methods may come to the attention of EPA.

Appendix A of report 2-14 includes a table of sources of data for use in the risk level approach. Appendix B of report 2-14 includes a table of sources of data for use in the water quality based Approach. The contractor shall investigate whether data from these publications are appropriate for comparing with 2012 RWQC using the two approaches above. The criteria for determining appropriateness will be developed as part of task 2 of this work assignment. The EPA WAM will be involved in developing the criteria for determining appropriateness. It is expected that the form of the data in the publications may not be correct for the intended use in this work assignment. Therefore, if needed, the contractor in conjunction with the EPA WAM will seek raw data from authors where possible.

The contractor shall coordinate with the EPA WAM in the collection of datasets from various sources (e.g.,Southern California Coastal Water Research Project (SCCWRP) and Water Environment Research Federation (WERF)).

Collection of datasets will be conducted such that the Office of Management and Budget (OMB) Information Collection Rule (ICR) will not be triggered.

Develop analysis plan and conduct analysis

Completion of the analysis plan and analysis are dependent on contractor receiving draft proposed RWQC numeric values from EPA. Some datasets can be identified and obtained before draft proposed RWQC numeric values are available.

The contractor shall develop an analysis plan considering the obtained datasets and the two approaches. Upon EPA WAM approval, the contractor shall evaluate the two approaches to determine the robustness and relevance with respect to 2012 RWQC. The sample datasets for the new methods will be compared to sample datasets from methods used in the 2012 RWQC. Approved datasets will be provided by EPA and are likely to be from NEEAR studies and/or other studies using EPA approved methods. The contractor shall incorporate additional studies into the analysis if data are available.

Report findings

The contractor shall submit a draft report of findings, including any recommendations for addressing potential "problem areas" in the analysis and potential use of the results in RWQC implementation. The contractor shall incorporate any additional analyses into revisions of the draft report upon receipt of additional datasets from EPA WAM.

EPA is interested in focusing on the performance of these methods to show that a common risk level can be applied resulting in a similar health protection standard for all CWA purposes. The two approaches should be developed such that there is clear statistical support for how the approaches can be used to link new methods/technology to 2012 RWQC implementation without undertaking any additional epidemiological studies.

It is of paramount importance that incorporation of the new methods/technology should result in equivalent health protection. EPA is interested in methods that may be incorporated for water quality assessment in the future as well as those that may be adopted in the near term, including those that can possibly be incorporated into water quality standards in the absence of epidemiological studies.

The report will include discussion of the strength of the statistical support for both approaches and possible limitations with the approaches.

Travel: Local travel is anticipated for this Task. No travel outside of the Washington, D.C. metro area is required.

Task 3: Multiple indicators measured together that result in combined risk: develop framework and collect and collate all the available information

This task is not under current budget

In addition to the two approaches evaluated in Task 2, another approach outlined in report 2-14 is supported in this task.

Modeling Approach - Multiple Indicators Measured Together that Result in Combined Risk

Some water quality indicators may be related to fecal pollution sources but not to adverse health effects as measured in epidemiology studies. This approach for incorporating alternative methods into RWQC without conducting additional epidemiological studies is to use alternative data (e.g., physical conditions at a beach) to relate beach water quality to specific fecal pollution. Use of sanitary surveys, pilot monitoring programs, and modeling appears to be the best way to connect site conditions to fecal pollution sources. Models that might be used in this mode include QMRA and regression models, such as those used to develop the Nowcasting schemes in use at some Great Lakes beaches.

When multiple indicators (biological and non-biological) are used, estimated risks could be binned and action levels could relate to whether or not a group of measurements fell within a particular bin. For example, below certain levels of combined indicators, no public health concern would be expected. When a different number of risk factors are observed, then a tool box approach could be used to determine any actions that are required. Above even greater thresholds of combined indicators, more aggressive public health protection steps would be required, such as an immediate beach closure.

Identify, collect, and collate studies

The contractor shall identify, collect, and collate the available studies/information related to indicators (biological and non-biological) used in beach modeling. These studies may be available in the published peer review literature, state-sponsored reports, EPA reports, and other Federal Agency reports (specifically USGS and USDA). The contractor shall coordinate with the EPA WAM as to the sources of these studies. The contractor shall search the following DIALOG databases: Biosis, NTIS, Enviroline, EMBASE, Water Resource Abstracts, Pascal, MedLine, FEDRIP, and Global Health. It is the goal of EPA to gather as many examples as possible to help inform the development of implementation policies and guidance related to 2012 RWQC. The contractor shall provide a bibliography for this task. It is EPA's concern that contractor shall include a list of references used for this task. In addition, contractor shall also include a list of unused references along with clear justification for not using them.

Summary of findings

The contractor shall prepare a summary of the literature. This summary will not be a comprehensive literature review that describes each study and the implications of that study to RWQC. This summary will provide an overview of the types of data being used in current modeling projects and the extent to which similar data exist that could be incorporated into future modeling efforts.

Collated report

The contractor shall collate the report from task 2 and the summary from task 3 into a combined report. The collated report will incorporate comments from the EPA WAM on the draft deliverables.

Travel: Local travel is anticipated for this Task. No travel outside of the Washington, D.C. metro area is required.

Task 4: Develop Technical Support Documents

In order to develop Technical Support Documents for criteria implementation, EPA is anticipating detailed analyses of the Task 2 that shall be the basis of completing Task four. This work shall provide a tool for states to develop new methods or indicators for their water quality standards on a site-specific basis. Information on demonstrating the relationship between two-indicator method combinations shall be characterized under this task. The contractor shall be aware of the following time-line to generate the deliverable. The deliverable will go for internal/management review followed by the external peer review. Afterwards, the peer reviewed deliverable will again be evaluated by internal/management team.

Draft deliverable and Charge to Internal Reviewer (ORD/HECD) After April 1, 2012

- Response/Incorporation – May 1- 15, 2012
- Management review - May 15 – June 7, 2012
- Peer review contract - To place
- Peer review package to ERG – July 15, 2012
- Final Peer Review Report - August 30, 2012
- Response to peer review comments – August 15- 30, 2012
  And incorporation of any changes to the deliverable (ICF)

After Peer Review

- Internal Review HECD - September 1 – 15, 2012
- Management review - September 21 – October 7, 2012
- Final deliverable - October 2012

Period of Performance/Milestones: It is the Contractor's responsibility to coordinate with EPA WAM while conducting these tasks.

Task	Milestone	Date due
1	Work Plan	Within 2 weeks of receipt of WA
1	1.1 QAPP	Within 3 weeks of receipt of WA
1	Kick-off meeting with EPA WAM	1 week after WP approval
2	Selection of new Indicators/Methods	1week after WP approval
2	Collection of data sets from various sources in conjunction with EPA	1/2 month after WP approval
2	Develop analysis plan in conjunction with EPA, including EPA approval of plan	1 months after WP approval
2	Conduct Statistical analysis and compare method performance	1.5 months after WP approval
2	Submit draft report of initial findings	2.5 months after WP approval
2	Incorporate additional studies into analyses, if identified (Task 2)	Incorporate any additional analyses into revisions to draft report upon receipt from EPA
3	Identify, collect and collate available studies	TBD
3	Submit draft report of initial findings	TBD
3	Incorporate additional studies, if identified	TBD
4	Draft Report	3 months after WP approval
2&4	Revised Report	TBD

Knowledge and Skills Required: Contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this work assignment. The Contractor shall have practical experience in statistical methods and have analysis and have advanced credentials in environmental microbiology. The contractor shall be familiar with the use of fecal indicator organisms, microbiological analytical methods (including molecular techniques) water monitoring, applications of epidemiological data, determination of human exposure to environmental contaminant sources, and gastrointestinal disease endpoints, and other factors associated with needs in recreational water quality and CWA 304(a) criteria development.

General Requirements of the Work Assignment and Schedule:

Due Dates: The Contractor shall provide due dates that are mutually acceptable with the EPA WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.

Delays: The Contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.

Draft Documents: The Contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. EPA WAM will provide comments on draft submissions prior to submission of final documents.

Final Documents: The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM.

Final Documents: The Contractor shall revise and incorporate all EPA's comments and submit final documents both electronically and in hardcopy (Microsoft version 2003 or higher) to EPA WAM. The Agency may decide to publish the report on the web. If this occurs, the report will need to be 508 compliant and the COR will provide appropriate technical direction.

Final Peer Reviewed Document: Upon receipt of the EPA's external expert peer-review of the Contractor's Final Written Report, the EPA WAM will provide the Contractor with the recommended edits and modifications. The Contractor shall address all recommended peer-review modifications. Changes will be documented in a separate report for the record to describe how the peer-review comments were incorporated into the final report. The Contractor shall provide the revised final report (and documented changes to the report) to the EPA WAM for review. Upon the EPA WAM's approval, the Contractor shall send the final revised peer-reviewed report in Microsoft Word, version 2003 or higher, to the EPA WAM.

Attachment 1
QAPP REQUIREMENTS FOR PROJECTS USING SECONDARY DATA

A secondary data project involves the gathering and/or use of existing environmental data for purposes other than those for which they were originally collected. These secondary data may be obtained from many sources, including literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. For these projects, a QAPP shall be prepared to include the requirements identified below. If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the secondary data. The following requirements should be addressed as applicable.

SECTION 1.0, PROJECT OBJECTIVES, ORGANIZATION, AND RESPONSIBILITIES

1.1 The purpose of study shall be clearly stated.
1.2 Project objectives shall be clearly stated.

1.3 The secondary data needed to satisfy the project objectives shall be identified. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable, shall be specified.

1.4 The planned approach for evaluating project objectives, including formulas, units, definitions of terms, and statistical analysis, if applicable, shall be included.

1.5 Responsibilities of all project participants shall be identified, meaning that key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

SECTION 2.0 SOURCES OF SECONDARY DATA

2.1 The source(s) of the secondary data must be specified.
2.2 The rationale for selecting the source(s) identified shall be discussed.
2.3 The sources of the secondary data will be identified in any project deliverable.

SECTION 3.0 QUALITY OF SECONDARY DATA

3.1 Quality requirements of the secondary data must be specified. These requirements must be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if applicable. (If appropriate, a related QAPP containing this information can be referenced.)

3.2 The procedures for determining the quality of the secondary data shall be described.

3.3 If no quality requirements exist, this shall be stated in the QAPP. If no quality requirements exist or if the quality of the secondary data will not be evaluated by EPA, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the secondary data has not been evaluated by EPA for this specific application. The wording for the disclaimer shall be defined.

SECTION 4.0 DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION

4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.

4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.

4.3 The expected product document that will be prepared shall be specified (*e.g.*, journal article, final report, *etc.*).

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-04

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-11-005	01/01/2011 To 12/31/2012	QMRA Activites
	Base Option Period Number 1	

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	3.1, 3.3, 3.6

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 01/01/2012 To 12/31/2012

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

SFO (*Max 2*) ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 01/01/2011 To 12/31/2012 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee: — LOE:

Cumulative Approved: — Cost/Fee: — LOE:

Work Assignment Manager Name: John Ravenscroft (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1101 FAX Number:
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Other Agency Official Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Contracting Official Name: Sandra Stargardt-Licis (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2006 FAX Number:

Performance Work Statement
ICF Contract # EP-C-11-005
Work Assignment #1-04

Title: QMRA Activities to Support Criteria Development and Implementation

Work Assignment Manager: John Ravenscroft (Mail Code 4304T)
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Period of Performance: Work Assignment Issuance through December 31, 2012

**Note: No CBI data will be needed in the course of this work assignment.

LOE: 1640

Contractor PWS: 3.1, 3.3, 3.6

Background: EPA is on track to issue new CWA 304(a) Recreational Ambient Water Quality Criteria (AWQC) by December 2012. The science underpinning the new criteria describes human health effects and water quality studies conducted in waters impacted primarily by human sources of fecal contamination. EPA would like to better understand the risks associated with other fecal sources and the potential wet weather impacts on surface waters. Quantitative Microbial Risk Assessment (QMRA) has been identified as a tool that the Agency can use to complement existing health data and to better understand the relative risks associated with non-human fecal sources of surface water contamination. The Agency's previously supported QMRA efforts have indicated that there are potentially significant differences in health risks associated between sources of fecal contamination and additional efforts are needed to better inform the regulatory framework. This work assignment covers various aspects of further development and application of QMRA in support of Recreational AWQC development and implementation.

Task 1: Work plan, monthly progress reports and quality assurance

Task 1.1: Work plan

The contractor shall develop a work plan to address all tasks in this work assignment. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than $100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs delineated by the tasks in this WA. These reports should also indicate an estimate for the next month by task and if any lagging costs are expected. EPA realizes these estimates are just approximate values and is interested in having this information for internal budgeting purposes.

Task 1.2: Development of QMP and contract-level QAPP

Work assignment-specific QAPPs were developed and approved under B-04, Task 1.3. The QMP and contract-level QAPP are still under development and additional effort is required to finalize both documents. Once approved, the contract-level QAPP will supersede the work assignment-specific QAPPs. The EPA WAM does not anticipate that substantial effort will be required for this task; however, the Contractor should budget for some minor efforts at the beginning of the year and low level effort for the remainder of the option year. The Contractor shall periodically review the QMP and QAPP with the EPA WAM to ensure continued applicability of these documents to ongoing efforts covered by the PWS of this contract.

Task 1.3: Information Quality Guidelines

The Contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines and shall complete the Checklist for Influential Information as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. The EPA WAM will provide the checklist to the Contractor. The Contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the Contractor shall document the quality assurance procedures it used in developing the deliverables under this Work Assignment. The Contractor shall provide the memo at the time it delivers the Final Summary Report. As directed by the EPA WAM, the Contractor shall have a teleconference with the EPA WAM to discuss the Guidelines and the Contractor's role in completing the checklist.

Task 2: General Project Support and Development of Technical Support Guidance

EPA is planning to make available Quantitative Microbial Risk Assessment (QMRA) guidance to States for consideration in developing site-specific Water Quality Standards (WQS) packages. Task 2 comprises the different facets of the QMRA guidance project and includes project planning, communication strategies, and guidance document development.

Task 2.1: Project planning and management

The Contractor shall conduct project strategic planning in conjunction with the EPA WAM. The purpose of this subtask will be to develop a comprehensive plan that includes all related tasks and deliverables in the context of the Agency timeline for publishing Recreational Ambient Water Quality Criteria (AWQC) and implementation guidance. The plan will also describe how each task will aid EPA in meeting its goals in relation to QMRA and the technical support guidance for implementation.

This task will require contractor travel to HQ for an initial planning meeting and quarterly update meetings thereafter during the period of performance of this work assignment. All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the PO.

The Contractor shall provide personnel knowledgeable in QMRA and also project planning and management for this process. Expertise in Microsoft Project (v. 2007) is preferred. The initial meeting is crucial to the entire overall work assignment and therefore will need to occur soon after the work assignment is received by the Contractor. Additionally, weekly update meetings between the EPA WAM and the Contractor shall be scheduled.

Deliverables under this subtask will include updating (as needed) the Gantt chart timeline listing all QMRA-related work with interim and final deliverable dates and quarterly project updates delineated. Given that the various QMRA tasks, both previously conducted by HECD and under the current effort, have been conducted incrementally, these pieces fit together to form a substantive body of work for the Agency. As part of the deliverables under this subtask, the Contractor shall include a discussion on the Agency's QMRA goals and objectives and how each of the tasks supports them. It is hoped that this exercise will also help to identify any gaps that will need to be addressed prior to the publication of the implementation guidance. Project milestones provided in this work assignment may be impacted by the results of this project planning. Any differences identified in these due dates will need to be identified and communicated via technical direction from the EPA WAM.

Task 2.2: Project communication support:

The contractor shall, based on technical direction given by the EPA WAM, provide support in preparing interim project updates and other materials for internal and external audiences. These may include but are not limited to short briefing documents and PowerPoint presentations. The contractors may also be directed to participate in and/or conduct briefings and meetings. The Contractor may also be directed to prepare reports for communication outside the EPA based on deliverables generated by tasks under this work assignment. The Contractor shall coordinate with the EPA WAM for the proper timing and need for these activities. A weekly update call with the EPA WAM will be required for this task, as needed. One specific part of this task is the "P4" communications paper that was started last year. The Contractor shall continue to coordinate updating this paper to reflect comments from EPA OW and ORD. This paper shall be included into the information used to develop the Technical Support Guidance (TSG) Volume B (see below).

A second major area under this task is Quantitative Microbial Risk Assessment (QMRA) outreach support. The Contractor shall assist EPA WAM with internal and external outreach to EPA management, both at Headquarters and with Regional offices, States, and other Stakeholder groups.

EPA needs to communicate its efforts to a broad audience. From engaging other scientists on technical issues to discussing regulatory actions with stakeholders and the public, EPA needs to be keenly aware of effective communication strategies. For all tasks under this work assignment, the Contractor shall discuss with the EPA WAM ways to achieve effective communication objectives. The audience for specific deliverables may be different even though the analytical approach may be similar. Questions to cover with the EPA WAM should address the audience and purpose of the deliverable, ideas for finding effective presentation strategies, suggestions for achieving the communication objectives given differing formats (e.g., written versus oral). .

The Contractor may be requested to attend meetings of a scientific nature to present the results of the QMRA analyses to technical and non-technical audiences. Known at of the time of submission of this work assignment is the following:

> 2012 Great Lakes Beach Association (GLBA) annual meeting. The information on the 2012 meeting is yet to be announced, but the GLBA consistently holds this meeting in the fall of the year. The Contractor shall engage with the EPA WAM to evaluate whether the 2012 meeting would be a good venue to help communicate the QMRA framework for site-specific criteria development. Consideration should be given to timing and meeting topic.

Task 2.3: Development of QMRA Technical Support Guidance, QMRA framework:

The purpose of this task is to continue development and to produce communication materials for the use of QMRA in the development of site-specific recreational water criteria intended as the basis for water quality standards (WQS). Past efforts by the Contractor have concentrated

mainly on non-human sources, but the framework itself should be robust enough to consider other differences or site-specific characteristics.

The Contractor shall continue development of the Quantitative Microbial Risk Assessment (QMRA) framework for the purposes outlined above. This task shall build upon previous efforts conducted under B-04, Task 2.2 (QMRA guidance: how to conduct a QMRA for ambient waters, data needs and analytical approaches). The goal for this task will be to develop and to communicate the process by which QMRA can be used to derive alternative site-specific ambient water quality criteria for recreational use waters that will, in turn, be used to assemble a water quality standards (WQS) package. This deliverable is not the technical support guidance as detailed in other tasks below, but rather a description and discussion of the process and framework whereby QMRA could be used as a basis for a site-specific WQS package.

The deliverable shall address the way(s) a State can determine if any given site is a good candidate for the development of a site-specific water quality standards package based on a QMRA-derived criteria value. The Contractor shall include a discussion of the components of water quality standards package and how QMRA can assist in developing a site-specific water quality criteria value. To complete this part of the deliverable, the Contractor shall meet with the EPA WAM, WQS coordinators or other personnel in SHPD and the Regions. Logistics of these meetings may require the Contractor to attend meetings at EPA HQ. The Contractor shall address the differing approaches a State could use in running a QMRA (i.e., differing level of effort related to complexity of analysis).

The Contractor shall also consider the implications that the WQS package will be evaluated by EPA regional and headquarters personnel who will not necessarily have a technical background in microbiology, public health or risk assessment methodologies. Therefore, it will be ***critical*** that the Contractor consider the end-user audience as the deliverable is being developed. Technical material shall be transparently and sufficiently conveyed. The narrative shall be thoroughly developed and any graphical materials shall be explained completely. No assumption should be made that the audience will internalize figures or tables. These considerations are quite important as this material will be used to inform the policy decisions needed for QMRA to be used effectively. Much consideration should be given to the current paradigm in this area; end-users that are not familiar with risk assessment in general and hampered by misunderstandings related to the past and current technical bases for the nationally recommended recreational water quality criteria. It will be crucial that the Contractor develop effective communication and outreach materials if QMRA is to be applied effectively.

Task 2.4: Development of QMRA Technical Support Guidance, Volume A:

The purpose of this task is to develop a guide for use by States and localities for the purposes of deriving via the QMRA framework discussed in Task 2.3, site-specific criteria, notably for waters predominated by non-human sources of fecal contamination, for inclusion into WQS. This guide should also provide information to EPA Regions who are tasked to evaluate State WQS packages. Volume A of this guidance shall concentrate on how to determine if a water body is eligible for the development of site-specific criteria, what information can be used to provide a

line of evidence approach for determining sources of fecal contamination (i.e., how to build a sanitary characterization), differing approaches to conducting a Quantitative Microbial Risk Assessment (QMRA) (i.e., incorporate information from Task 2.3), the information needs for conducting a QMRA (at each level of effort), how to conduct a QMRA (i.e., how to build a transparent, clear, concise and reasonable risk assessment in support of public policy), deriving a site-specific water quality criterion, preparing a site-specific water quality standards package, and other topics as needed to be specified by the EPA WAM (and in consultation with HECD's partners in SHPD). The main goal for this deliverable is produce guidance for States to use in developing microbial Water Quality Standards (WQS) that are scientifically defensible, protective of the recreational designated use, and meet EPA standards for consideration and potential approval.

This task will require the Contractor to attend meetings with the EPA WAM and other staff at EPA Headquarters during the period of performance for the purposes of project updates, planning and communication. The Contractor shall anticipate travel to DC once per quarter for a total of 4 meetings at EPA HQ.

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the PO.

Task 2.5: Development of QMRA Technical Support Guidance (TSG), Volume B:

The deliverable under this task shall provide the end user a sufficiently detailed background on QMRA and the use of microbial risk assessment in developing site specific water quality standards. This volume shall provide the technical bases for the material in Volume A (Task 2.4). While this volume is purposefully technical in nature, it should still be produced in a manner that would be accessible to the end user.

The Contractor shall include the following topics in the scope of technical materials: assessing human health risks from fecal contamination in surface waters; use and application of epidemiology in development of water quality standards around the world; use of risk assessment to help interpret and extend observational studies; factors affecting occurrence, prevalence, fate and transport of pathogens and fecal indicator bacteria in surface waters; potential effects of management practices on sources of fecal contamination and implications to potential human health risks; and, other topics as specified by the EPA WAM.

Task 2.6: Development of QMRA Technical Support Guidance (TSG), Volume C:

The purpose of this task is to document a series of QMRAs conducted on recreational use waters. Each QMRA would be made available or peer reviewed/published separately. This volume will discuss each and give more information to explain how each risk assessment fits into context with the materials in volumes A and B. The context that will need to be developed

will consist of a compare and contrast discussion with EPA recommended ambient water quality criteria for recreational waters and other risk assessments. The Quantitative Microbial Risk Assessments (QMRAs) can be discussed as 'case studies'.

At present, the EPA WAM envisions this "volume" to comprise a report and will reference the risk assessments discussed and where to find them (should copyrights allow, those assessments can be included as appendices). Existing material for inclusion in this volume includes: Ohio case study; Boqueron case study, Chicago Area Waterways (CAWS) case study, and Southern California Coastal Water Research Project (SCCWRP) case study. However, the SCCWRP case study may not occur due to tightening budgets and lack of EPA resources. The Contractor shall coordinate with the EPA WAM early and often to better scope out other potential material for this volume.

An urgent deliverable (see milestone table) will be needed under this task within 2 weeks of receiving the work assignment. The Contractor shall, in conjunction with the EPA WAM, develop a cost estimate for pathogen (and Fecal Indicator Bacteria (FIB)) monitoring consistent with SCCWRP's study design for their case study QMRA project. The estimate will detail the resources needed to monitor for the microbes (FIB, pathogens, and Microbial Source Tracking (MST) markers). Data generated from such an estimate should be directly usable in conducting a QMRA in support of developing a site-specific water quality criterion.

The Contractor may be required to attend meetings with SCCWRP to discuss planning, scoping, conduct, or analyses associated with the case study project. As mentioned before, all appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the PO.

Task 3: QMRA anchoring

Task 3.1: Marine National Epidemiological and Environmental Assessment of Recreational Water (NEEAR) studies

A draft report was submitted by the Contractor on 11/30/11. The Contractor shall update the draft to reflect EPA comments. The results of this effort will be included in the TSG Volume B. The Contractor shall discuss with the EPA WAM the benefit of having the results peer reviewed by a scientific journal or as part of Volume B (and peer reviewed separately). Once updated (as discussed below), the Contractor shall also submit as part of the revised draft a project summary aimed at a non-technical audience. The summary should provide the important conclusions to be drawn from the analysis along with a discussion of how these results fit into context with the existing knowledgebase (not necessarily restricted to the area of QMRA).

The Contractor shall update the analysis of the QMRA anchoring report for the Surfside epidemiology study with the available sanitary characterization information. The source of fecal

contamination affecting the Surfside study area was determined to be non-human. Based on the observed source(s), as documented in OST's sanitary survey report, this Quantitative Microbial Risk Assessment (QMRA) should mirror previous efforts where non-human agricultural fecal sources were characterized.

As stated in the draft report, the results of the sanitary survey for Surfside beach, the available water quality data from the Surfside epidemiology study, a literature review on fecal indicator and pathogen densities in the relevant fecal contamination source for Surfside beach, and the previously developed QMRA methods should be integrated to update the draft analysis.

Task 3.2: Marion et al. study

A draft report was submitted in a memorandum by the Contractor in July 2011. EPA WAM provided comments on this memorandum. Additionally, EPA WAM, the Contractor and Ohio State University (OSU) staff met to discuss the QMRA and ways to improve the report for a final version that could be submitted for peer review. Dr. Jiyoung Lee of OSU shared additional data with EPA that should be considered in a revised QMRA. The Contractor shall continue to coordinate with EPA WAM and OSU in order to update the QMRA with additional information and/or analyses as identified in previous comments. The additional information includes, but not limited to: onset to illness data for swimmers; rainfall dates, including Army Core of Engineers gauge data and lake inflow data; and, additional monitoring data as appropriate (e.g., culture and Quantitative Polymerase Chain Reaction (qPCR) data for FIB, adenovirus occurrence, etc.). An updated report suitable for internal management review shall be submitted to EPA WAM within two weeks of the workplan approval. Comments from this review shall be discussed with the EPA WAM and the report revised accordingly. A final report suitable for peer review shall be submitted to EPA WAM by the end of March 2012.

This collaboration provides an excellent opportunity for the EPA to engage with external researchers. The Contractor shall assist in maintaining the good relationship EPA has established with the OSU staff. Any ideas for improving this collaboration will be quite welcome to the EPA WAM. Additionally, the contractor may be requested to provide facilitation assistance with the OSU group in order to maintain sufficient progress towards peer reviewing the QMRA schedule (see milestone table).

Task 3.3: Boqueron

The Contractor submitted a draft report on 11/11/11. The Contractor shall update the draft to reflect EPA comments. The Contractor shall submit an updated draft report, of sufficient quality for internal management review, within 1 month of receiving EPA comments. Any comments from this review shall be discussed with the EPA WAM and the report revised accordingly. A final report suitable for peer review shall be submitted to EPA by the end of April 2012.

The Contractor shall provide assistance to the EPA WAM in developing communication materials aimed at non-technical and technical audience. EPA WAM will be discussing the results of the Boqueron QMRA and monitoring study with stakeholders in Puerto Rico in

February 2012. The Contractor shall engage the EPA WAM within 2 weeks of receiving the work assignment to discuss the content and organization of these materials.

Task 3.4: QMRA anchoring communication support

The Contractor shall develop communication materials for each of the task 3 QMRA reports aimed at non-technical, policy-oriented audiences (see milestone table). Materials aimed at the general population may also be needed and shall be prepared by the contractor when technical direction is received. The Contractor shall discuss the importance of the findings of the Task 3 efforts, how they fit into context with other QMRA and other results, and any science or policy implications. Other topics to be included in these materials will be discussed as needed with the Contractor.

Additionally, the Contractor may be required to attend one or two planning meetings at EPA Headquarters to present results to management and staff. Timing for the meeting(s) has not been finalized at the time of the submission of this work assignment; however, ODCs for two visits to EPA Headquarters are included.

Task 4: Relative QMRA refinement

Task 4.1: Evaluating source and receptor locations

This task shall continue support for efforts begun under B-04. The contractor shall meet with the EPA WAM to develop a list of modeling needs (e.g., FRAMES-related) to support implementation of QMRA. The contractor shall also coordinate with the EPA WAM to discuss with other EPA personnel about advancements in dose response modeling (e.g., animal studies translated to human health estimates). This discussion should evaluate whether these advancements could be incorporated into the Microbial Risk Assessment Information Tool (MRA-IT) and then tailored to the FRAMES QMRA approach.

The contractor shall continue to discuss with the EPA WAM and ORD-Athens personnel the current capabilities for fate and transport modeling in the context using the QMRA framework for deriving water quality standards. HECD will need to have these discussions documented for use with communication with management.

Task 4.2: Relative QMRA refinement: QMRA analysis of mixed fecal sources

The Contractor submitted a draft memo discussing the analytical approach for conducting a QMRA evaluating human health risks from exposure to water impacted by mixed sources of fecal contamination (i.e., human and non-human FIB sources, human and non-human pathogen sources, and animal and non-fecal FIB sources) under B-04.

The Contractor shall update the draft memo incorporating EPA comments. An updated report suitable for internal management review shall be submitted to the EPA WAM within two weeks of the receiving EPA comments. Comments from this review shall be discussed with the EPA WAM and the report revised accordingly. A final report suitable for peer review shall be

submitted to the EPA WAM within two weeks of receiving comments from the management review.

Task 5: Primary and Secondary Contact evaluations

The purpose of this task is to evaluate health risks associated with different water-based activities performed in the US. This task will be part of the scientific basis for policy measures to place activities into appropriately protective recreational use categories (e.g. primary contact recreation, secondary contact recreation), and to determine the level of water quality necessary to protect individuals engaging in each of these activities.

The Contractor submitted a draft Quantitative Microbial Risk Assessment (QMRA) report during the base year under this task. For this work assignment, the Contractor may be asked to provide responses to questions from EPA WAM on the analysis and conclusions contained in the deliverable. The Contractor should consider this task 'low level of effort' for purposes of developing the workplan.

Task 6: Children's Health, Sensitive Subpopulations, Alternate Study designs, and Environmental Justice evaluations

Task 6.1: QMRA approaches to evaluate risks to sensitive subpopulations and children's health.

The Contractor submitted a draft deliverable in the base year under this task. This task is being removed from this work assignment and included with 1-07 since that work assignment specifically addressed children's health, sensitive subpopulations and environmental justice issues.

Task 6.2: Alternate epidemiology study designs

EPA is interested in comparing results from epidemiology studies conducted with alternative study designs. The Agency has conducted past efforts in this area to identify appropriate data sets and design an analytical approach for that data. The Contractor shall build upon those past efforts and secure data from an RCT (randomized control trial) epidemiology study sufficient for a comparative analysis with a PC (prospective cohort) design. The Contractor shall conduct the following activities:

Coordinate with the investigators on an RCT study to obtain the raw data from that study and re-analyze the results using the statistical methods employed by Wade and colleagues for the EPA epidemiology studies. This analysis will provide an indication of whether or not results from RCTs and PCs can be compared directly and will help to answer the question of whether the differences observed in existing epidemiology studies are due to the study design or other factors.

Use a QMRA framework to translate results from an RCT to one that is comparable to a PC study. Conduct sensitivity analyses to identify the model parameters that most strongly

influence the results. Compare the results with those from #1. The contractor shall report findings to EPA WAM in a memorandum, including potential next steps for this analysis.

Efforts conducted in the base year resulted in the identification of potential datasets for this analysis. However, there has been reluctance from external researchers to share the data needed for this comparison. This subtask is included here to maintain the potential for this analysis in the option year, but the Contractor should consider this subtask as a placeholder and low priority. Should data become available, the Contractor shall discuss the path forward with the EPA WAM before any LOE is expended on this task.

Task 7: Chicago Area Waterways (CAWS) QMRA

The goal of this task is to develop a QMRA-based evaluation of human health risks from exposure to the Chicago Area Waterways. This evaluation should consider the range of exposures covered by the traditional metrics of primary and secondary contact recreation. The QMRA analysis and characterization include and build upon previous work under B-04 Task 5. The Agency previously provided comment on both the CAWS QMRA conducted by the Metropolitan Water Reclamation District of Greater Chicago (MWRDGC) and the Chicago Health Environmental Exposure and Recreation Study (CHEERS) epidemiology study led by Sam Dorovitch of U. of Illinois at Chicago. Both studies suffer from design constraints and the Agency is unsure how to properly interpret the results.

The Contractor submitted a draft QMRA using both literature-reported values for pathogens in secondary treated, but non-disinfected effluent and the results from pathogen monitoring on the CAWS. The EPA WAM sent comments on this draft on December 21, 2011. These comments will need to be addressed in the next version of the report (see milestone table).

The Contractor shall evaluate the following points and questions in the revised QMRA (this list is not exhaustive and other points/questions/comments may arise from the technical discussion between ICF and EPA):

- Estimate illness from "primary" and "secondary" exposure to treated POTW effluent (e.g., 'end of pipe' exposure to secondary treated effluent with and without disinfection). Also, conduct the same analysis for exposure to CSO-impacted waters. This analysis must be accompanied by a thorough discussion, including non-technical presentations of data, analysis, and results. The discussion should cover potential implications for interpreting the RWQC.
    - Use literature values for human sewage for pathogens and FIB.
    - Use literature values for treatment efficacy on both groups of microbes; include chlorination and UV.
    - Incorporate fate and transport information.
    - Address the following questions:
        - Given the epidemiological relationships observed at POTW-impacted beaches and how those relationships inform the level of protection for the recommended RWQC, what is the expected

level of protection at the end of pipe? Conversely, what would be an equally protective criteria at the POTW compared to the beach? (address these questions in terms of FIB – culture and molecular-based enumerations – and with pathogens like norovirus (reference) or enteroviruses in general)

- Compare this analysis with analyses based on the CAWS data.
  - Are available microbial data are reflective of the prevailing wet and dry conditions within the CAWs. Was the existing pathogen monitoring sufficient? Were sampling locations sufficient to represent the conditions expected to occur (e.g., wet weather and CSO events)?

- How do the estimated probabilities of illness compare to the observational results from the CHEERS epi study? What can be said about the other illness endpoints that seemed important from the epi study results (e.g., AFRI, eye, etc.)? Would those alternative endpoints be affected by disinfection (i.e., while the draft report addressed the effect of disinfection on GI illness, would not the effect actually be more pronounced as can be seen in the CHEERS study?)?
- Include estimates of illness for primary contact activities and include analyses and discussion that compares and contrasts the differences for high, middle and low ingestion activities. Can a similar approach to binning these activities as was discussed with B-04 task 5 be taken here?
- Include the relative QMRA step. What does the illness estimate translate into in terms of FIB? Relate this to potential primary and secondary contact WQS for the CAWs.
- Can one derive a secondary contact recreational water quality criteria based on the QMRA framework utilized in this exercise? (If so, how? Discuss.)
- Does using a probabilistic analysis increase confidence in the estimated probabilities of illness compared to the static analysis?

There is considerable interest within EPA, both at HQ and in Region 5, in this particular QMRA. While this is not a final expectation, the Contractor may be requested to visit Region 5 in order to discuss other potential analyses. This visit is not definite, but ODCs have been included in case the need for the meeting materializes.

The Contractor shall revise the draft as a risk assessment for informing policy decisions. While it is fine to use the MRA tools document as a starting guide, the Contractor shall be mindful that EPA has a long history of using risk assessments in support of decision making, so this QMRA should reflect existing Agency guidance on risk assessment.

The Contractor shall submit technical and non-technical briefing materials along with the revised assessment. These materials may be a "two-pager" and/or a slide presentation and will be discussed during the weekly meeting.

General Requirements of the Work Assignment and Schedule:

Due Dates: The Contractor shall provide due dates that are mutually acceptable with the EPA WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.

Delays: The Contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.

Draft Documents: The Contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. EPA WAM will provide comments on draft submissions prior to submission of final documents.

Final Documents: The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM.

Milestone/Deliverable Table

Task	Task #	Milestones and Due Dates
Task 1: Work plan, monthly progress reports and quality assurance		
Workplan	1.1	Within 15 calendar days of receipt of work assignment
Development of QAPP and QMP	1.2	Within 15 calendar days of receipt of work assignment
Information Quality Guidelines	1.3	Discuss with EAP WAM within 15 calendar days of receipt of work assignment. IQG checklists due with final deliverable (can be included with QA materials).
Task 2: General Project Support		
Project Planning and Management	2.1	Initial planning meeting to be held within 15 calendar days of receipt of work assignment. Meeting shall update project Gantt chart, goals and objectives statement, and gap analysis due within 2 weeks of initial meeting. Drafts of this deliverable would be expected at the close of the initial meeting. Subsequent meetings to be held roughly every quarter thereafter.
Project Communications Support	2.2	After the workplan approval, throughout the period of performance. See meeting dates in WA text. Other communication materials will be dependent on the analytical results. Revisions to the P4 paper due within 2 weeks of receiving comments from OW and ORD.
QMRA TSG: QMRA Framework	2.3	Draft for internal review, 3/15/12 (communication materials included); Final by 4/30/12 contingent on EPA comments.
QMRA TSG: Vol A	2.4	Draft for internal review: By 5/16/12; Draft for peer review, 6/19/12; Draft final by 10/31/12; Final by 11/28/12
QMRA TSG: Vol B	2.5	Draft for internal review, by 10/16/12; draft for peer review by 11/27/12; *Draft final by 3/29/13; Final by 5/30/13*

QMRA TSG: Vol C	2.6	Vol C mainly consists of reports prepared individually under other tasks - refer to those tasks for component schedules. For supplemental text expanding on those reports: Ohio, Boqueron and CAWS case study text (draft by 8/15/12; final within 2 weeks of receiving EPA comments). Develop cost estimate for reference pathogen testing using SCCWRP study design, within 2 weeks of receiving work assignment.
Task 3: QMRA Anchoring		
Marine NEEAR reverse QMRA	3.1	Updated draft within 1 month of receiving EPA comments. Discuss incorporation of results into TSG Vol B and venue for peer review and publication at weekly WA meeting at weekly meeting.
Marion anchoring QMRA	3.2	Update draft report based on EPA and OSU comments and other analyses, with 2 weeks of workplan approval. Updated draft will be reviewed by HECD management. Mgmt comments will be addressed and final report to be submitted for peer review by end of March, 2012.
Boqueron QMRA	3.3	Updated draft within 1 month of receiving EPA comments. Updated draft will be reviewed by HECD mgmt. Mgmt comments will be addressed and final report to be submitted for peer review by end of April, 2012.
QMRA Communications Support	3.4	Non-technical, policy oriented communication materials, within 1 month of workplan approval. Materials for general audiences due date to be determined by technical direction. Meeting and presentation at EPA HQ to be determined.
Task 4: Relative QMRA refinement		

Evaluating sources and receptor locations	4.1	Ongoing throughout the period of performance. Periodic teleconference calls (e.g., bimonthly) with HECD, ICF, and ORD-Athens. Deliverables for this task include notes of teleconference meetings and synopses of modeling developments and capabilities used for internal communication.
Refinement of QMRA analyses of mixed fecal sources	4.2	Updated draft within 2 weeks of receiving EPA comments. Updated draft will be reviewed by HECD mgmt. Mgmt comments will be addressed and final report to be submitted for peer review 2 weeks after receiving EPA management comments.
Task 5: Primary and Secondary Contact		
Communications support		Low LOE effort; as needed throughout the period of performance.
Task 6: Sensitive Subpopulations and alternate study designs		
Sensitive subpops and children's health	6.1	Moved to 1-07
Alternative epidemiology study design	6.2	Low LOE effort; continue efforts to identify RCT data sets.
Task 7: CAWS QMRA support		
Update draft QMRA addressing EPA comments and inclusion of additional questions/information.	7.1	Updated draft within 1 month of workplan approval. Progress to be discussed at weekly meetings with WAM. Updates shall be reflective of EPA comments, and the draft shall include and fully discuss the necessary context information and be aimed at the appropriate audience.
Produce communication materials for non-technical audience	7.2	Submitted with updated draft. Content and format to be discussed at weekly WA meetings.
Include probabilistic parameters and analysis to updated risk assessment and identification and inclusion of Region 5-specific questions/concerns.	7.3	Refinement of revised draft (7.1) upon receiving EPA comments and planning discussion with EPA WAM. Discussion due within 15 days of receiving EPA comments, QMRA refinements due within 1 month of receiving EPA comments.

Attachment 1
QAPP REQUIREMENTS FOR PROJECTS USING SECONDARY DATA

A secondary data project involves the gathering and/or use of existing environmental data for purposes other than those for which they were originally collected. These secondary data may be obtained from many sources, including literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. For these projects, a QAPP shall be prepared to include the requirements identified below. If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the secondary data. The following requirements should be addressed as applicable.

SECTION 1.0, PROJECT OBJECTIVES, ORGANIZATION, AND RESPONSIBILITIES

1.1 The purpose of study shall be clearly stated.
1.2 Project objectives shall be clearly stated.

1.3 The secondary data needed to satisfy the project objectives shall be identified. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable, shall be specified.

1.4 The planned approach for evaluating project objectives, including formulas, units, definitions of terms, and statistical analysis, if applicable, shall be included.

1.5 Responsibilities of all project participants shall be identified, meaning that key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

SECTION 2.0, SOURCES OF SECONDARY DATA

2.1 The source(s) of the secondary data must be specified.
2.2 The rationale for selecting the source(s) identified shall be discussed.
2.3 The sources of the secondary data will be identified in any project deliverable.

SECTION 3.0, QUALITY OF SECONDARY DATA

3.1 Quality requirements of the secondary data must be specified. These requirements must be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if

applicable. (If appropriate, a related QAPP containing this information can be referenced.)

3.2 The procedures for determining the quality of the secondary data shall be described.

3.3 If no quality requirements exist, this shall be stated in the QAPP. If no quality requirements exist or if the quality of the secondary data will not be evaluated by EPA, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the secondary data has not been evaluated by EPA for this specific application. The wording for the disclaimer shall be defined.

SECTION 4.0, DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION

4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.

4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.

4.3 The expected product document that will be prepared shall be specified (e.g., journal article, final report, etc.).

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-04

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-11-005	01/01/2011 To 12/31/2012	QMRA Activities to Support Cri
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: 3.1, 3.3, 3.6

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 01/01/2012 To 12/31/2012

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (Max 2): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period:	Cost/Fee:	LOE:
01/01/2011 To 12/31/2012		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: John Ravenscroft (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 202-566-1101	
	FAX Number:	
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 202-566-1107	
	FAX Number:	
Other Agency Official Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 202-566-1107	
	FAX Number:	
Contracting Official Name: Sandra Stargardt-Licis (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 513-487-2006	
	FAX Number:	

Performance Work Statement
ICF Contract # EP-C-11-005
Work Assignment #1-04 Amendment 1

Title: QMRA Activities to Support Criteria Development and Implementation

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Period of Performance: Work Assignment Issuance through December 31, 2012

**Note: No CBI data will be needed in the course of this work assignment.

Please note that this task list is a supplement to WA 1-04; only the pertinent changes to that list (i.e., the additional tasks) are denoted here. The original task list still applies.

Background: Same as the original work assignment

Task 1: Work plan, monthly progress reports and quality assurance

Task 1.1: Work plan – Same as the original work assignment
Task 1.2: QAPP requirements for Task 2.6 and 2.7 – Attachment 1 and 2

Task 2: General Project Support and Development of Technical Support Guidance

EPA is planning to make available Quantitative Microbial Risk Assessment (QMRA) guidance to States for consideration in developing site-specific Water Quality Standards (WQS) packages. Task 2 comprises the different facets of the QMRA guidance project and includes project planning, communication strategies, and guidance document development.

Task 2.6: Development of QMRA Technical Support Guidance (TSG), Volume C:

The purpose of this task is to document a series of QMRAs conducted on recreational use waters. Each QMRA would be made available or peer reviewed/published separately. This volume will discuss each and give more information to explain how each risk assessment fits into context with the materials in volumes A and B. The context that will need to be developed will consist of a compare and contrast discussion with EPA recommended ambient water quality criteria for recreational waters and other risk assessments. The QMRAs can be discussed as 'case studies'.

At present, the EPA WAM envisions this "volume" to comprise a report and will reference the risk assessments discussed and where to find them (should copyrights allow, those assessments can be included as appendices). This document should discuss in layman's terms the interpretation and implications of the referenced studies. This volume need not be limited to EPA-sponsored QMRA documents should other high quality QMRAs be available in the scientific literature or from other governmental agencies. For example, the application of microbial risk assessment in New Zealand for deriving health protective water quality standards for *E. coli* based on the occurrence of *Campylobacter* from sheep may be a good example of the flexible, yet robust, nature of the risk assessment framework. An additional example of using a QMRA-based approach to designate appropriate water body uses in Australia may be worth covering in this report. For non-EPA examples, a discussion comparing and contrasting the approached used compared to EPA's QMRA framework within the context of the Clean Water Act will be necessary. Existing EPA-sponsored material for inclusion in this volume includes: Ohio case study; Boqueron case study, Chicago Area Waterways (CAWS) case study, and Southern California Coastal Water Research Project (SCCWRP) case study.

As discussed in more detail in Task 2.7 below, the SCCWRP case study project is beginning later this year. The Contractor shall coordinate with the EPA WAM to plan how to incorporate the SCCWRP study results into the QMRA TSG. The Contractor shall also evaluate how the technical results could inform refinement of the QMRA framework, if needed, and how the policy component of deriving a site-specific water quality standard can be incorporated into the TSG.

Task 2.7: Support for Southern California Coastal Water Research Project (SCCWRP) case study

The LA Regional Water Control Board, Ventura Co. Watershed Protection District, SCCWRP and EPA are collaborating on a project to characterize human health risks via QMRA from recreational water exposure at a predominantly non-human fecal-impacted beach in Southern California. The potential beach locations are in Ventura County, CA. The second main goal of this effort is to use the QMRA results to inform the development of a site-specific water quality standard for submission and evaluation by EPA Region 9. The third goal of this effort is to document the experience as a "case study" for potential application at other candidate sites.

Results from this effort will be used to compile three primary reports that will form the basis for achieving the three project goals. First, a technical results report will be written by the project group to estimate the potential human health risks from recreational exposure at the study beach and to inform the derivation of a site-specific water quality objective based on an equivalent benchmark level of public health protection as discussed in EPA's recommended recreational water quality criteria. Second, a 'policy' report would discuss how to develop a site-specific alternative water quality standard, from a process viewpoint, based on the results contained in the technical report and would cover Federal, state, and local considerations. Finally, a non-technical communications package would be developed for use in engaging stakeholders, higher level management, and the public. This package would provide a layman's version of the study purpose, design, and results through plain language outreach materials.

The Health and Ecological Criteria Division's participation in this project will be to aid in the planning and scoping of the project, provide QMRA support, and engage the regional water control board, EPA Region 9, and the local non-government organizations (NGOs) in the development and evaluation of a site-specific water quality standard package. The Contractor shall assist the EPA WAM with the QMRA-related aspects of this project. The Contractor shall participate in discussions with the EPA WAM along with SCCWRP and the workgroup to help with project planning, scoping, QMRA analysis, interpretation of the results, and development of communication strategies for the purpose of deriving site-specific recreational water criteria for a beach predominantly impacted by non-human fecal contamination. Study details related to timing and schedules are not yet finalized, but should be by June 2012. QMRA-related efforts under this task should help to inform activities under Task 2.6. The Contractor shall discuss the practical experiences learned from this project to help improve, refine, or change the current approach detailed in the TSG.

Workgroup meetings are anticipated to occur approximately once per quarter in the greater Los Angeles, CA area. The Contractor may be required to attend these meetings to supply QMRA-related expertise and guidance to the workgroup on the scientific and technical aspects of the project. All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the PO.

General Requirements of the Work Assignment and Schedule:

Due Dates: The Contractor shall provide due dates that are mutually acceptable with the EPA WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.

Delays: The Contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.

Draft Documents: The Contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. EPA WAM will provide comments on draft submissions prior to submission of final documents.

Final Documents: The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM.

Milestone/Deliverable Table

Task	Task #	Milestones and Due Dates
Task 1: Work plan, monthly progress reports and quality assurance		
Workplan	1.1	Within 15 calendar days of receipt of work assignment
Task 2: General Project Support		
QMRA TSG: Vol C	2.6	Coordinate with EPA WAM to evaluate impact of SCCWRP study on TSM. Assess potential impacts and plan and scope potential TSM refinements based on case study experience. Ongoing low level effort throughout the period of performance.
Support for SCCWRP study	2.7	Provide QMRA related planning, scoping, analysis, interpretation, and site-specific standard derivation support. Attend workgroup meetings at SCCWRP approximately one per quarter. Ongoing low level of effort throughout the period of performance.

Attachment 1
QAPP REQUIREMENTS FOR PROJECTS USING SECONDARY DATA

A secondary data project involves the gathering and/or use of existing environmental data for purposes other than those for which they were originally collected. These secondary data may be obtained from many sources, including literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. For these projects, a QAPP shall be prepared to include the requirements identified below. If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the secondary data. The following requirements should be addressed as applicable.

SECTION 1.0, PROJECT OBJECTIVES, ORGANIZATION, AND RESPONSIBILITIES

1.1 The purpose of study shall be clearly stated.
1.2 Project objectives shall be clearly stated.

1.3 The secondary data needed to satisfy the project objectives shall be identified. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable, shall be specified.

1.4 The planned approach for evaluating project objectives, including formulas, units, definitions of terms, and statistical analysis, if applicable, shall be included.

1.5 Responsibilities of all project participants shall be identified, meaning that key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

SECTION 2.0, SOURCES OF SECONDARY DATA

2.1 The source(s) of the secondary data must be specified.
2.2 The rationale for selecting the source(s) identified shall be discussed.
2.3 The sources of the secondary data will be identified in any project deliverable.

SECTION 3.0, QUALITY OF SECONDARY DATA

3.1 Quality requirements of the secondary data must be specified. These requirements must be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if applicable. (If appropriate, a related QAPP containing this information can be referenced.)

3.2 The procedures for determining the quality of the secondary data shall be described.

3.3 If no quality requirements exist, this shall be stated in the QAPP. If no quality requirements exist or if the quality of the secondary data will not be evaluated by EPA, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the secondary data has not been evaluated by EPA for this specific application. The wording for the disclaimer shall be defined.

SECTION 4.0, DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION

4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.

4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.

4.3 The expected product document that will be prepared shall be specified (e.g., journal article, final report, etc.).

Attachment 2
QAPP Requirements for Research Model Development and Application Projects

GENERAL REQUIREMENTS: Include cover page, distribution list, approvals, and page numbers.

0. COVER PAGE (MODEL DEVELOPMENT AND MODEL APPLICATION)

Include the Division/Branch, project title, revision number, EPA technical lead, QA category, organization responsible for QAPP preparation, and date.

1. PROJECT DESCRIPTION AND OBJECTIVES (MODEL DEVELOPMENT AND MODEL APPLICATION)

In this document, "project" can mean (a) development or substantial modification of a model for application to address a general problem; (b) application of an existing model (including minor modification to the existing model) to address a specific problem; or (c) a development or substantial modification and application of a model to address a specific problem.

1.1 State the purpose of the project and list the project objective(s). Indicate whether a new model will be developed or an existing model will be used.

1.2 Describe the problem, the data to be generated by the model, how the data will be used to address the problem, and the intended users of the data. Describe the environmental system/setting to be modeled, where the model will be applied, and the circumstances and scenarios to be considered for the modeled system.

2. ORGANIZATION AND RESPONSIBILITIES (MODEL DEVELOPMENT AND MODEL APPLICATION)

2.1 Identify all project personnel, including QA, and related responsibilities for each participating organization, as well as their relationship to other project participants.

2.2 Include a project schedule that includes key milestones.

3. MODEL SELECTION (MODEL APPLICATION ONLY)

3.1 Discuss model selection with respect to how it will be used and how it is consistent with the project objectives. Include fundamental details such as whether the model will be used to predict the world beyond the model or in scenario analysis of the model itself. Describe the limits to where the model is applicable.

3.2 Provide a description of the model attributes/capabilities required for the project. This description should include hardware requirements and restrictions. Provide an overview of the candidate model attributes, including:

- model origin and its original purpose, if applicable
- model structure (e.g., stochastic vs. deterministic, structural framework)
- parameters and variables
- the algorithms and equations that have been developed to support the model theory, along with the sources of the algorithms
- spatial extent (individual, group, population)
- spatial resolution (location independent/dependent, dimensionality)
- temporal extent (length of modeling period)
- temporal resolution (time step)

3.3 Identify the model to be used or, if the model has not yet been selected, describe the process to be used for the selection of an existing model.

3.4 Identify specific requirements for application of the selected model for this specific purpose (e.g., current and appropriate data, parameter values, assumptions).

4. MODEL DESIGN (MODEL DEVELOPMENT ONLY)

4.1 Describe the conceptual model(s) for the system, including model parameters.

4.2 Identify algorithms and equations that have been developed to support the model theory, or if such equations are not already available, describe the process used to develop these equations.

4.3 Specify required sources for model databases and any requirements for these data (e.g., quality, quantity, spatial, and temporal applicability). If data sources are not currently known, describe the criteria used to identify sources. Describe how any data gaps will be filled.

5. MODEL CODING (MODEL DEVELOPMENT ONLY)

5.1 Discuss the requirements for model code development, where applicable.

5.2 Identify computer hardware and software requirements.

5.3 Discuss requirements for code verification.

6. MODEL CALIBRATION (MODEL DEVELOPMENT AND MODEL APPLICATION)

Calibration is the process of adjusting model parameters within physically defensible ranges until the resulting predictions give the best possible or desired degree of fit to the observed data. Calibration should be applied each time the model is modified.

6.1 Discuss how the model will be calibrated.

6.2 Identify the type and source of data (e.g., new data, existing data, professional judgment, expert opinion elicitation) that will be used to calibrate the model, including any requirements for the data (quality, quantity, and spatial and temporal applicability). If data sources are not currently known, describe the criteria used to identify sources.

6.3 Specify acceptance criteria which need to be met for the difference between

predicted and observed data during model calibration, where applicable. The statistical methods (e.g., goodness-of-fit, regression analyses) or expert judgment to be used should also be discussed.

7. MODEL VERIFICATION (MODEL DEVELOPMENT AND MODEL APPLICATION)

Verification consists of comparing the predictions of a calibrated model with available data that were not used in the model development and calibration.

7.1 Discuss the approach to be used for model verification. Describe how the verification is appropriate based on the model's purpose. Identify the type and source of data (e.g., new data, existing data, synthetic test data sets, professional judgment, expert opinion elicitation) that will be used to verify the model. If data sources are not currently known, describe the criteria used to identify sources.

7.2 Discuss the characterization of model uncertainty (model framework, model input, and model applicability) and sensitivity (model application only).

7.3 Describe any requirements (quality, quantity, and spatial and temporal applicability) for the data that will be used to verify the model.

7.4 Describe the approach used to determine if the independent data verify the model predictions. Specify the criteria which need to be met for the difference between predicted and observed data for the model to be considered to be verified. Discuss any statistical methods to be used (e.g., goodness-of-fit, regression analyses).

8. MODEL EVALUATION (MODEL DEVELOPMENT AND MODEL APPLICATION)

8.1 List and describe the qualitative or quantitative assessment process to be used to generate information to determine whether a model and its analytical results are of a quality sufficient for the intended use.

8.2 List and describe any independent/external evaluation and review of the model and model design, such as scientific peer review.

9. MODEL DOCUMENTATION (MODEL DEVELOPMENT AND MODEL APPLICATION)

Specify the requirements for model documentation. Good documentation includes:

- final model description, final model specifications (model development only), hardware and software requirements, including programming language, model portability, memory requirements, required hardware/software for application, data standards for information storage and retrieval
- the equations on which the model is based (model development only)
- the underlying assumptions
- flow charts (model development only)

- description of routines (model development only)
- data base description
- source code (model development only)
- error messages (model development only)
- parameter values and sources
- restrictions on model application, including assumptions, parameter values and sources, boundary and initial conditions, validation/calibration of the model, output and interpretation of model runs (model development only)
- the boundary conditions used in the model
- limiting conditions on model applications, detail where the model is or is not suited
- changes and verification of changes made in code
- actual input data (type and format) used
- overview of the immediate (non-manipulated or -post processed) results of the model runs (model application only)
- output of model runs and interpretation
- user's guide (electronic or paper)
- instructions for preparing data files (model development only)
- example problems complete with input and output
- programmer's instructions
- computer operator's instructions
- a report of the model calibration, validation, and evaluation (model development only)
- documentation of significant changes to the model
- procedures for maintenance and user support, if applicable

10. REPORTING (MODEL DEVELOPMENT AND MODEL APPLICATION)

10.1 List and describe the deliverables expected from each project participant.

10.2 Specify the expected final product(s) that will be prepared for the project (e.g., journal article, final report).

11. REFERENCES

Provide the references either in the body of the text as footnotes or in a separate section.

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-04

☐ Other ☒ Amendment Number: 000002

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-11-005	01/01/2011 To 12/31/2012 Base Option Period Number 1	QMRA Activities to Support Cri

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: 3.1,3.3,3.6

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 01/01/2012 To 12/31/2012

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
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4										
5										

Authorized Work Assignment Ceiling

Contract Period: 01/01/2011 To 12/31/2012 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee: — LOE:

Cumulative Approved: — Cost/Fee: — LOE:

Work Assignment Manager Name: John Ravenscroft (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1101 FAX Number:
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Other Agency Official Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Contracting Official Name: Sandra Stargardt-Licis (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2006 FAX Number:

Performance Work Statement
ICF Contract # EP-C-11-005
Work Assignment #1-04 Amd 2

Title: QMRA Activities to Support Criteria Development and Implementation

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Period of Performance: WA Amendment Issuance through December 31, 2012

**Note: No CBI data will be needed in the course of this work assignment.

Contractor PWS: **3.1, 3.3, 3.6**

Please note that this task list is a supplement to WA 1-04; only the pertinent changes to that list (i.e., the additional tasks) are denoted here. The original task list still applies.

Purpose of Amendment: The purpose of this amendment is to expand on Task 2.4 and add two new tasks, 2.8 and 2.9. This amendment will specify additional task efforts for the development of Volume A of the QMRA Technical Support Materials, development of communication materials for the technical support materials, and updating the draft Microbial Risk Assessment tools document in preparation for publication. The Contractor, in conjunction with the EPA WAM, shall review and evaluate these activities in regards to the scope of the currently approved contract-level QAPP.

Background: same as original WA

Task 1: Work plan, monthly progress reports and quality assurance

Task 1.1*: Work plan – same as original WA*

Task 2.4: Development of QMRA Technical Support Materials, Volume A

Ongoing efforts in the development of Volume A have resulted in identification of an additional element that needs to be addressed in the document. The intended audiences of the support materials include local and state regulatory entities who wish to potentially develop site-specific water quality standards, as well as, the corresponding EPA staff at headquarters and in the various regions who would be evaluating the standard package submission in terms of scientific defensibility and protectiveness of the designated use. At present, Volume A does not include input from those audiences on the elements that the end users would find helpful. The Contractor shall conduct a follow up engagement with the appropriate stakeholders, especially those who submitted public comments on the draft criteria document, to gather feedback on the technical support material elements. Specifically, feedback user-friendliness, clarity, transparency, and other elements as identified by the EPA WAM should be collated for evaluation by EPA.

Task 2.8: Development of Communication Materials for the Technical Support Material documents

Currently, OST plans to publish technical support materials to cover the subject areas mentioned in Section 5 of the draft recreational water quality criteria document as posted in December 2011. There is a need to produce a guide to the technical support materials (TSM) to aid the end user on which subject area may apply in their situation and when they have a good candidate waterbody for developing a site-specific water quality criterion. The summary document should also provide a high level discussion, although providing more detail than is contained in the draft criteria document, covering each subject area and why the end user might want to consider expending effort and resources to develop site-specific water quality criteria. A 'question/answer' format for part of the document may be helpful for communicating the concepts. This 'Guide to the TSMs' shall be prepared in conjunction with the development of the individual TSM documents and shall be completed by October 31, 2012. Additionally, the Contractor shall prepare and submit communication materials to be used for internal EPA discussions.

Task 2.9: Updating the Microbial Risk Assessment Tools Document

OST previously prepared a microbial risk assessment (MRA) document specifically for water media. This document has been through internal editing and peer reviewed by the EPA's Science Advisory Board. While the document is fairly complete at this stage, OST needs a few minor modifications made so that the document can be finalized by management and published on the EPA website. The EPA WAM will provide document to the contractor. The Contractor shall make the following modifications to the document:

1) Update the secondary transmission discussion with newer references.
2) Review the reference section and double check the 'in press' status of references cited.
3) Add an appendix to provide a crosswalk between the "Tools" document and EPA eco risk assessment guidance.
4) Provide additional discussion in section 1 on the application of MRA to decision-making. (see eco risk guidance for ideas)
    a. This discussion shall reinforce the concepts that risk assessments are routinely used for informing science policy and policy decisions.
    b. The discussion shall also cover the similarities of the MRA framework and other risk assessment frameworks routinely used by the Agency (e.g., eco risk).
    c. The discussion should reference the appendix under #3 on this list.
5) Provide additional discussion, mainly in section 1, on the interaction between the risk assessor and risk manager and/or communicator.
    a. While the figures suggest that these three functions occur separately, in reality, the risk assessor inhabits the area where all three overlap, as shown in the Venn diagram in figure 1 in the document.
    b. Given the audience of this document, as stated on page 4, is mainly EPA staff and Agency risk assessment activities rarely exist is a complete vacuum apart from the risk management and communication activities, there is a need to highlight the importance of these functions and how this interaction can impact the risk assessment process.
6) Prepare document for 508 compliance
7) Fix Exec Summary, paragraph 2, 1st sentence to read: This Microbial Risk Assessment (MRA) tools, methods, and approaches document ("MRA Tools") was developed to assist EPA and others in conducting MRAs—including quantitative microbial risk assessments (QMRAs[1])—that are well documented and are respected by the scientific community.
8) Update section 5.6 to reflect additional QMRA work published by OST since the SAB peer review occurred.

The revised document should need a final internal QA check by the Contractor prior to submission to the EPA WAM. The Contractor shall also develop a briefing package for the document to be used in communicating with internal EPA management in the document approval process. The briefing package should include a brief synopsis of the document and potential questions and answers geared toward non-risk assessors.

Task No.	Milestones/Deliverable*	Schedule
1	1.1 Workplan	Within 15 business days of receipt of WA
2.4	Follow up with stakeholder comments on technical support materials. *submit memo to EPA WAM discussing the results	Within 3 weeks of approval of workplan
2.8	*Submit draft "guide to TSMs"	By Aug 1, 2012
2.8	Respond to EPA comments	Within 2 weeks of receiving EPA comments
2.8	*Submit final 'guide to TSMs"	NLT October 31, 2012;note: this date may change due to EPA needs
2.8	*Submit internal briefing material on TSM documents to EPA WAM	By Aug 31, 2012
2.9	Modify MRA tools document as specified	Within 2 weeks of workplan approval
	*Submit updated MRA tools document to EPA WAM	Within 2 weeks of completed modifications.
	*Submit briefing package for MRA Tool document	Within 2 weeks of completed modifications

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-04

☐ Other ☒ Amendment Number: 000003

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-11-005	01/01/2012 To 12/31/2012 Base Option Period Number 1	QMRA Activities

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: 3.1,3.3,3.6

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 01/01/2012 To 12/31/2012

Comments:
WORK ASSIGNMENT 1-04 HAVE BEEN FULLY FUNDED AT THE COST OF $256,586

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (Max 2) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
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Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 01/01/2012 To 12/31/2012		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: John Ravenscroft (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1101 FAX Number:
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Other Agency Official Name (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Sandra Stargardt-Licis (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2006 FAX Number:

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-07

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-11-005	01/01/2011 To 12/31/2012 Base Option Period Number 1	Children's Risks from Fecal Co

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: 3.1,3.3,3.6

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 01/01/2012 To 12/31/2012

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

SFO (Max 2): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
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Authorized Work Assignment Ceiling

Contract Period: 01/01/2011 To 12/31/2012 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee: — LOE:

Cumulative Approved: — Cost/Fee: — LOE:

Work Assignment Manager Name: John Ravenscroft (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1101 FAX Number:
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Other Agency Official Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Contracting Official Name: Sandra Stargardt-Licis (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2006 FAX Number:

Performance Work Statement
ICF Contract EP-C-11-005
Work Assignment #1-07

Title: Children's risks from fecal contamination in recreational water

Work Assignment Manager: John Ravenscroft (Mail Code 4304T)
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Period of Performance: Work Assignment Issuance through December 31, 2012

Contractor SOW: 3.1, 3.3, 3.6

****Note: No CBI data will be needed in the course of this work assignment.**

Goal: The overall goal of this Performance Work Statement (PWS) is to examine multiple lines of evidence (Center for Disease Control (CDC) Recreational Water Illness outbreak data, risk assessment analyses and epidemiological data) to evaluate the potential that children have disproportionate risks of waterborne illness from recreational water contact.

Objectives:

1. Produce a comprehensive report for internal EPA evaluation detailing the known health information for children's waterborne illnesses from recreational water exposure. The report shall demonstrate an evaluation of the scientific literature, risk analysis (e.g., QMRA) and observational results (e.g., National Epidemiological and Environmental Assessment of Recreational Water (NEEAR) study reports).
2. Produce a draft and final report for external scientific peer review based on the information covered in objective 1.
3. Produce communications materials to accompany reports including: a one (1) to

two (2) page nontechnical synopsis, a technical summary document written in non-academic style for a non-scientific audience, a 'questions and answers' (Q&As) document covering areas of potential inquiry from nontechnical and technical audiences (both internal and external), and others as determined by the EPA WAM via technical direction.

Methodology:

1. The Contractor shall combine previous efforts under WA B-07 and B-04 task 6.1 to compile a comprehensive evaluation of the potential health impacts on children from exposure to fecally-contaminated recreational water. This evaluation shall compare and contrast the potential health effects on the general population, as discussed in the current revisions of EPA's recreational water criteria for ambient waters.
2. The Contractor shall utilize the draft memos, including the data summary tables, prepared under WA B-07, including:
    a. Children's health risks from infectious and pathogenic microorganisms
    b. Identification of waterborne microorganisms associated with recreational water illness
    c. Children's risks from fecal contamination in recreational water: epidemiological study review
    d. Analysis of outbreak data for waterborne pathogens associated with recreational water illness in children: ambient/surface waters in the U.S.
3. The Contractor shall utilize the draft analysis detailed in the B-04 task 6.1status update memo, "QMRA approaches to evaluate risks to sensitive subpopulations and children's health."
4. The Contractor shall specifically address the following questions in the conduct of this assignment :
    a. Is there evidence for increased risk/illness for children compared to adults and/or the general population from exposure (any body contact; swimming, wading, ingestion, hand to mouth contact) to fecal contamination?
    b. If so, can this difference be accounted for in recreational water quality determinations as measured by fecal indicator bacteria (FIB)?

Background: A growing body of scientific knowledge has demonstrated that children may suffer disproportionately from environmental health risks and safety risks. These risks occur because 1) children's neurological, immunological, digestive, and other bodily systems are still developing; 2) children eat more food, drink more fluids, and breathe more air in proportion to their body weight than adults; 4) children's size and weight may diminish their protection from standard safety features; and 5) children's behavior patterns may make them more susceptible to accidents because they are less able to protect themselves.

The importance of identifying and assessing risks to children was made in Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risk[1], which states:

> "to the extent permitted by law and appropriate, and consistent with the agency's mission, each Federal agency:
>
> (a) shall make it a high priority to identify and assess environmental health risks and safety risks that may disproportionately affect children; and (b) shall ensure that its policies, programs, activities, and standards address disproportionate risks to children that result from environmental health risks or safety risks.
>
> 1-102. Each independent regulatory agency is encouraged to participate in the implementation of this order and comply with its provisions."

The U.S. Environmental Protection Agency (EPA)'s Policy on Evaluating Risks to Children[2] :

> "considers the risks to infants and children consistently and explicitly as a part of risk assessments generated during its decision making process, including the setting of standards to protect public health and the environment. To the degree permitted by available data in each case, the Agency will develop a separate assessment of risks to infants and children or state clearly why this is not done - for example, a demonstration that infants and children are not expected to be exposed to the stressor under examination."

The US EPA's Office of Children's Health Protection[3] conducts research and supports risk assessments to assess children's risks and susceptibility to environmental contaminants (chemicals, toxins, air pollutants). However, it not clear whether children suffer disproportionate exposures and health outcomes as a result of exposure to pathogens such as found in recreational surface waters. Few epidemiological data and quantitative risk assessments have explored children's risks from microbial contaminants found in water, limiting the ability to determine if children experience different responses to waterborne fecal indicators and pathogens, or develop illness rates as a result of recreational water contact in the United States. Risks in children have specifically not been explored separately, but they are included as part of the general populations in most epidemiological studies.

Under the auspices of the Clean Water Act (CWA), the Agency regulates recreational water, and sets numeric indicator bacteria criteria (*Escherichia coli*, Enterococci) in surface (ambient) waters used for the purpose of recreational water contact. The current

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[1] Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks. http://yosemite.epa.gov/ochp/ochpweb.nsf/content/whatwe_executiv.htm

[2] Policy on Evaluating Health Risks to Children. http://www.epa.gov/osa/spc/pdfs/memohlth.pdf

[3] The Office of Children's Health Protection. http://yosemite.epa.gov/ochp/ochpweb.nsf/content/whatwe_executiv.htm

recreational water criteria were designed to protect swimmers (in general) from illnesses due to exposure to pathogens in recreational waters. The criteria developed in 1986 were mainly based on enumerations of fecal indicator bacteria (FIB) using culture-based methods. EPA is committed to develop new recreational water quality criteria for all water body types by 2012 and will address potentially disproportionate risks to children in the criteria development process.

Epidemiology studies have been conducted to describe and quantify the health effects associated with exposure to contaminated recreational waters. The primary goal of most of these studies has been to evaluate associations between measures of microbial water quality (usually quantified by measuring fecal indicator bacteria) and swimming-associated illness.

To address this issue, variations of two basic study designs have been used. For the purposes of this Work Assignment, these study designs are referred to as the "cohort" and the "randomized" design. The cohort design was used in the EPA epidemiology studies. The U.S. EPA, in collaboration with the Centers for Disease Control and Prevention have undertaken The National Epidemiological and Environmental Assessment of Recreational (NEEAR) Water Study to investigate human health effects and rapid water quality methods associated with recreational water use. A main goal of the NEEAR study is to determine how new ways of measuring fecal pollution can be used effectively to protect swimmers' health. The randomized design has been used in studies in Europe.

The approach of these designs differs in several critical aspects, some of which are summarized briefly below.

Swimmer/non-swimmer assignment:
The randomized design assigns "swimming" and non-swimming status by randomly assigning participants to each exposure group. The cohort design uses observed and self-reported swimming status. In the randomized design, swimmers are asked to swim completing specific activities such as immersing their head and/or staying in the water for a minimum amount of time at a designated position. In the cohort design, locations and swimming are assessed by interviewer and self-report.

Target population:
The EPA NEEAR cohort studies target the beach going population as their target population sample, and population of interest. Randomized trials often recruit subjects from nearby communities. Due to ethical issues, many randomized trial studies restrict their enrollment to adults 18 and over.

Water quality assessment and exposure assignment:
The randomized study usually attempts to assign individual exposures by intensively characterizing the water quality where an individual swimmer is exposed. However, there are known sampling and matrix issues with assigning water quality, as measured by fecal indicator bacteria, to individual swimmers.

Detection of indicator bacteria does not necessarily track the occurrence or distribution of pathogens that may or may not be present in the water column. Water quality in a cohort study is usually characterized by collecting samples in a fixed layout to assess average water quality over a given time/space dimension.

Other differences:
Because the cohort design is less intensive with regard to resources and investigator involvement, usually more subjects are enrolled over a wider range of days and environmental conditions. The EPA NEEAR Water Study has focused on FIB measured by novel and rapid analytical methods; whereas all published randomized designs have relied on traditional methods and approaches in measuring indicator bacteria.

Quality Assurance: The tasks in this PWS require the use of secondary data/analyses and fall under the scope of the approved contract-level QAPP. Consistent with the Agency's quality assurance (QA) requirements, the contractor must assure the quality and analyses of the secondary data and other data collected to be used under this PWS.

The Contractor shall discuss with the EPA WAM if any of the specific work assignment tasks are not readily covered under the approved QAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a WA-specific QAPP supplement, which must be approved by the EPA WAM before activities covered by the additional QA language begin under this PWS..

Performance Work Statement (PWS): The scope in this PWS will fall under the following task areas:

Task 1: ***Work Plan and monthly progress reports (MPR)***

Task Area 1.1. Work Plan
The contractor shall develop a work plan to address all tasks in this work assignment. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than $100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

Task Area 1.2. Monthly Progress Reports
This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoiced LOE and costs delineated by the

tasks in this WA. The Contractor shall provide the EPA WAM with weekly updates detailing progress. That updates shall be provided every Friday via email.

Task Area 1.3. Information Quality Guidelines
The Contractor shall ensure the products developed under this PWS comply with the EPA Information Quality Guidelines and shall complete the Checklist for Influential Information as needed for each deliverable from this PWS as they may be used in Agency decision-making and/or will be publicly available documents. The EPA WAM will provide the checklist to the Contractor. The Contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the Contractor shall document the quality assurance procedures it used in developing the deliverables under this PWS. The Contractor shall provide the memo at the time it delivers the Final Report under Task 2.1. As directed by the EPA WAM, the Contractor shall have a teleconference with the EPA WAM to discuss the Guidelines and the Contractor's role in completing the checklist.

Task Area 2*: Project Reports*

Task Area 2.1. Preparation of EPA report detailing results
The Contractor shall prepare and submit a comprehensive report for under this task detailing the information collected an analyzed for the evaluation of human health risks to children from recreational exposure to fecal contamination. The report shall capture information evaluated as specified in the above sections.

The Contractor shall conduct a project planning meeting in conjunction with the EPA WAM prior to compiling the report. This meeting will include the following topics: how to utilize the existing information reported in the B-07 memos and B-04 QMRA to compile this report, identify any additional analyses that may be needed, how to detail the overall messages in an accessible format, what additional narrative needs to be developed to effectively communicate the analytical results and contextual public health message (i.e., incorporating effective risk communication tools in the report to engage both the technical and non-technical audiences), what additional communication materials would be needed (see Task 3), project scheduling, and other topics to be determined.

The report may undergo multiple edits and the Contractor is expected to respond to EPA comments. This document will need to be formatted as directed by the EPA WAM. The Contractor shall incorporate comments on any draft deliverables from EPA WAM. Also, the Contractor shall update information in the report as needed to capture any developments related to ongoing studies. The report shall be compliant with Section 508 of the Rehabilitation Act when finalized and submitted (see http://www.epa.gov/accessibility/index.htm).

Task Area 2.2. Preparation of Report of External Scientific Peer Review
The Contractor shall prepare and submit a version of the final report based on the deliverable under Task 2.1 that would be suitable for external scientific peer review. This task is subsequent to task 2.1. The Contractor shall submit a draft to the EPA WAM for Agency clearance. When all Agency comments have been addressed, that version may be submitted for peer review. The venue for the peer review is currently undetermined. The Contractor shall address peer reviewer comments in conjunction with the EPA WAM. This document will need to be formatted for publication as directed by the EPA WAM.

Task Area 3: *Communication materials*

As specified in the above methodology section, the Contractor shall prepare, in conjunction with the EPA WAM, materials to assist in communicating the complex technical aspects of the project results to both non-technical and technical (but not academic) audiences (both internal and external to the Agency). These materials will most likely consist of synopses, executive summaries, Q&As, presentation slides, etc. and each may be aimed at a particular audience or to tailored for the communication need. The Contractor shall coordinate with the EPA WAM on the scope and nature of these materials for specific audiences.

Task Area 4: *General Project Support*

The Contractor shall, based on technical direction given by the EPA WAM, provide support in preparing interim project update and/or other materials for internal and external audiences. These may include, but are not limited to, short briefing documents and PowerPoint presentations. The contractor may also be directed to participate in and/or conduct briefings and/or present at meetings. It is estimated that this task should not require more than 5 – 10 % of the total LOE allotted to this work assignment.

One of the outcomes of the project planning meeting detailed in Task 2.1 may be the identification of data or analysis gaps, particularly in regards to the QMRA analysis. For example, the finalized analysis of the NEEAR marine data was not completed at the time of the conduct of the QMRA under B-04, task 6. Although the final analysis of that data did not show a significant difference in illness response between children 12 and under and the general population, using this combined dataset may be helpful for the discussion of the QMRA portion of the deliverables under tasks 2.1 and 2.2. Should such analyses be identified as important based on the outcome of the project planning meeting, the EPA WAM will provide technical direction to ICF.

The Contractor shall plan on attending one presentation at EPA HQ at the draft report stage to discuss findings. All appropriate clearances and approvals required by Agency policy in support of any and all meetings shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under meeting-

related activities and expenses shall not occur until this approval is obtained and provided by the PO.

Task No.	Milestones/Deliverable*	Schedule
1	1.1 Workplan	Within 15 business days of receipt of WA
1	1.3 Information Quality Guidelines	Submitted with final deliverables
2	2.1 Project planning meeting.	Within 2 weeks of receipt of WA
2	2.1 Compile literature information and risk analyses; identify any remaining data/information gaps and ways to address in the report; *submit memos to EPA WAM discussing: 1) project plan for combining the children's health info and identify data and analysis gaps with remedial approach; and 2) communication strategy.	Within 2 weeks of 2.1 planning meeting
2	*2.1 Draft report for EPA review	Within 3weeks of 2.1 planning meeting
2	2.1 Respond to EPA reviewer comments	Within 2 weeks of receiving EPA comments
2	*2.1 Submit final report to EPA	Within 2 weeks of addressing comments
2	*2.2Submit draft report for EPA review	TBD based on outcome of Task 2.1
2	2.2 Respond to EPA reviewer comments	Within 2 weeks of receiving EPA comments
2	*2.2 Submit final report to EPA for peer review clearance	Within 2 weeks of addressing comments
3	Prepare risk communication presentation materials for technical and non-technical audiences	TBD by technical direction
4	General project support	TBD by technical direction

Travel: Local travel is required for contractor to attend one presentation at EPA HQ. Otherwise, *no* contractor travel outside of the Washington, D.C. metro area is anticipated for this PWS.

Task Knowledge and Skills Required: The Contractor shall have expertise in preparing the materials associated with this work assignment and be knowledgeable with the various fields of discipline discussed. The Contractor shall also be proficient in R programming and other relevant statistical tools. The Contractor shall have practical

experience in environmental microbiology, epidemiology, and statistical methods and analysis and have advanced credentials in statistics or environmental engineering. The Contractor shall be familiar with the different programs under the CWA, use of water quality monitoring, determination of human exposure to environmental contaminant sources, and gastrointestinal (or other) disease endpoints, applications of epidemiological data, and other factors associated with needs in recreational water quality and CWA 304(a) criteria development.

The Contractor shall also be able to communicate the study outcomes and recreational outbreak data to a non-technical audience.

General Requirements of the Work Assignment and Schedule:

Due Dates: The Contractor shall provide due dates that are mutually acceptable with the EPA WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.
Delays: The Contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.
Draft Documents: The Contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. EPA WAM will provide comments on draft submissions prior to submission of final documents.
Final Documents: The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM.

Attachment 1
QAPP REQUIREMENTS FOR PROJECTS USING SECONDARY DATA

A secondary data project involves the gathering and/or use of existing environmental data for purposes other than those for which they were originally collected. These secondary data may be obtained from many sources, including literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. For these projects, a QAPP shall be prepared to include the requirements identified below. If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the secondary data. The following requirements should be addressed as applicable.

SECTION 1.0, PROJECT OBJECTIVES, ORGANIZATION, AND RESPONSIBILITIES

1.1 The purpose of study shall be clearly stated.

1.2 Project objectives shall be clearly stated.

1.3 The secondary data needed to satisfy the project objectives shall be identified. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable, shall be specified.

1.4 The planned approach for evaluating project objectives, including formulas, units, definitions of terms, and statistical analysis, if applicable, shall be included.

1.5 Responsibilities of all project participants shall be identified, meaning that key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

SECTION 2.0, SOURCES OF SECONDARY DATA

2.1 The source(s) of the secondary data must be specified.

2.2 The rationale for selecting the source(s) identified shall be discussed.

2.3 The sources of the secondary data will be identified in any project deliverable.

SECTION 3.0. QUALITY OF SECONDARY DATA

3.1 Quality requirements of the secondary data must be specified. These requirements must be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if applicable. (If appropriate, a related QAPP containing this information can be referenced.)

3.2 The procedures for determining the quality of the secondary data shall be described.

3.3 If no quality requirements exist, this shall be stated in the QAPP. If no quality requirements exist or if the quality of the secondary data will not be evaluated by EPA, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the secondary data has not been evaluated by EPA for this specific application. The wording for the disclaimer shall be defined.

SECTION 4.0, DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION

4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.

4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.

4.3 The expected product document that will be prepared shall be specified (*e.g.*, journal article, final report, *etc.*).

References

CDC Rec Water Outbreaks:

Alphabetical index of Water-Related Health Data:
http://www.cdc.gov/healthywater/statistics/surveillance/health_data.html

CDC Healthy Swimming Webpage: http://www.cdc.gov/healthywater/swimming/data/

Epidemiological studies:

"High Sensitivity of Children to Swimming-Associated Gastrointestinal Illness Results Using a Rapid Assay of Recreational Water Quality" Timothy J. Wade, Rebecca L. Calderon, Kristen P. Brenner, Elizabeth Sams, Michael Beach, Richard Haugland, Larry Wymer, and Alfred P. Dufour (Epidemiology 2008;19: 375–383)
http://journals.lww.com/epidem/Abstract/2008/05000/High_Sensitivity_of_Children_to.8.aspx

Marine Studies (P1, 2):
"Rapidly measured indicators of recreational water quality and swimming-associated illness at marine beaches: A prospective cohort study" Timothy J Wade , Elizabeth Sams, Kristen P Brenner , Rich Haugland , Eunice Chern , Michael Beach , Larry Wymer, Clifford C Rankin , David Love , Quanlin Li , Rachel Noble and Alfred P Dufour - Environmental Health 2010, 9:66doi:10.1186/1476-069X-9-66
Published: 31 October 2010
• Table S2: Adjusted Odds Ratios for illness risk among swimmers for a 1 log10 Increase in indicator density. Children age 10 and under.
http://www.ehjournal.net/imedia/3968942414721357/supp2.pdf

Epidemiological study in marine waters impacted by urban runoff in a temperate region (CD 5(a)):
"Report on 2009 National Epidemiologic and Environmental Assessment of Recreational Water Epidemiology Studies" Timothy J Wade , Elizabeth A Sams, Rich Haugland, Kristen P Brenner, Quanlin Li, Larry Wymer, Marirosa Molina, Kevin Oshima and Alfred P Dufour. US Environmental Protection Agency, Office of Research and Development; 2010.USEPA Report Number: EPA/600/R-10/168.
• Table 4.5, 4.6: Water exposures among children
• Tables 4.8-4.12: Incidence of illness among children
• Table 4.39, 4.42, 4.56, 4.57,
• Figure 5.16: Incidence of illness among children with regard to measures of water quality.
http://water.epa.gov/scitech/swguidance/waterquality/standards/criteria/health/recreation/index.cfm

Epidemiological study in a tropical region (CD 5(b)):

"Report on 2009 National Epidemiologic and Environmental Assessment of Recreational Water Epidemiology Studies" Timothy J Wade , Elizabeth A Sams, Rich Haugland, Kristen P Brenner, Quanlin Li, Larry Wymer, Marirosa Molina, Kevin Oshima and Alfred P Dufour. US Environmental Protection Agency, Office of Research and Development; 2010.USEPA Report Number: EPA/600/R-10/168.

Wade, T. J., R. L. Calderon, et al. (2006). "Rapidly measured indicators of recreational water quality are predictive of swimming-associated gastrointestinal illness." Environ Health Perspect 114(1): 24-8.

Wade, T. J., N. Pai, et al. (2003). "Do U.S. Environmental Protection Agency Water Quality Guidelines for Recreational Waters Prevent Gastrointestinal Illness? A Systematic Review and Meta-analysis." Environmental Health Perspectives 111(8): 1102-1109.

Colford, J. M., Jr., T. J. Wade, et al. (2007). "Water Quality Indicators and the Risk of Illness at Beaches With Nonpoint Sources of Fecal Contamination." Epidemiology 18(1): 27-35.

Fleisher, J. M., F. Jones, et al. (1993). "Water and non-water-related risk factors for gastroenteritis among bathers exposed to sewage-contaminated marine waters." International Journal of Epidemiology 22(4): 698-708.

Fleisher, J. M., D. Kay, et al. (1996). "Marine waters contaminated with domestic sewage: nonenteric illnesses associated with bather exposure in the United Kingdom." Am J Public Health 86(9): 1228-34.

Kay, D., J. M. Fleisher, et al. (1994). "Predicting likelihood of gastroenteritis from sea bathing: results from randomised exposure." Lancet 344(8927): 905-9.

Wiedenmann, A., P. Kruger, et al. (2006). "A randomized controlled trial assessing infectious disease risks from bathing in fresh recreational waters in relation to the concentration of Escherichia coli,
intestinal enterococci, Clostridium perfringens, and somatic coliphages." Environ Health Perspect 114(2): 228-36.

Kay, D., N. Ashbolt, et al. (2006). "Reply to comments on "Derivation of numerical values for the World Health Organization guidelines for recreational waters"." Water Res 40(9): 1921-5.

Kay, D., J. Bartram, et al. (2004). "Derivation of numerical values for the World Health Organization guidelines for recreational waters." Water Res 38(5): 1296-304.

A description of EPI-BATHE can be found:
http://www.aber.ac.uk/iges/research/epibathe/favorite.htm

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-08

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-11-005	01/01/2011 To 12/31/2012 Base Option Period Number 1	AWQC for Pathogens

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	3.1,3.3,3.4,3.6

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 01/01/2012 To 12/31/2012

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (Max 2): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 01/01/2011 To 12/31/2012		0
This Action:		760
Total:		760

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Sharon Nappier (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 202-566-0740	
	FAX Number:	
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 202-566-1107	
	FAX Number:	
Other Agency Official Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 202-566-1107	
	FAX Number:	
Contracting Official Name: Donna Reinhart (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 513-487-2114	
	FAX Number:	

PERFORMANCE WORK STATEMENT

TECHNICAL AND REGULATORY SUPPORT FOR THE DEVELOPMENT OF CRITERIA FOR WATER MEDIA (MICROBIOLOGY EMPHASIS)

1.0 INTRODUCTION

1.1 Background

The mission of the United States Environmental Protection Agency's Office of Water (OW) under the Safe Drinking Water Act and the Clean Water Act includes protecting the public health from the adverse effects of microbial pollutants (e.g., chemicals and microorganisms) in media such as surface water, drinking water, wastewater, sewage sludge, and sediments. In fulfillment of this mission, OW's Office of Science and Technology (OST) develops effluent guidelines, human health criteria, implementation guidance for health advisories, maximum contaminate level goals, and limits for pollutants in various water media.

1.2 Purpose of Contract

The purpose of this contract is to provide technical and regulatory support services to the Health and Ecological Criteria Division (HECD) in OST for the development of human health criteria, implementation guidance for health advisories, maximum contaminate level goals, and pollutant limits concerning the adverse effects of microbial pollutants in media such as surface water, drinking water, wastewater, sewage sledge and sediments. This support includes direct activities and related activities such as conducting literature reviews, conducting risk assessments, performing statistical analyses, evaluating pollutants selected for review by the United States Environmental Protection Agency (EPA), assessing the potential impact of criteria on sensitive populations, preparing criteria documents, preparing health advisories, preparing technical guidance documents, preparing technical support documents for regulatory requirements, preparing the index of references for proposed and final regulations, summarizing comments on proposed regulations, and arranging and conducting workshops.

2.0 GENERAL TASKS

2.1 The contractor shall furnish all facilities, materials, equipment, and necessary professional, technical, and support personnel in support of the effort delineated below. The initial submission of all documents shall be in draft form for EPA review and comment. Required revisions will be provided to the contractor by EPA for incorporation into a final document.

2.2 The contractor shall possess or have access to appropriate equipment/software to perform mathematical modeling and statistical analyses in support of criteria development.

2.3 The contractor shall develop documents and data bases using EPA standard software (e.g., Word, Excel, and Lotus Notes), as specified in a work assignment. Software documentation shall be accessible to the EPA Work Assignment Manager (WAM) and other persons authorized by the EPA Project Officer (PO).

2.4 The contractor shall possess or have access to a laboratory that can analyze microbial pollutants (e.g., standard analytical methods for pathogens including molecular methods) in water media (e.g., wastewater, ground and or surface water, drinking water, sediment and sewage sludge), hereinafter referred to as water media, as specified in a work assignment. The contractor shall prepare a Quality Assurance Project Plan (QAPP) for work assignments that require environmental measurements or the use of secondary data.

2.5 The contractor shall provide information that will be used by EPA for quick responses and analyses of options, issues, and policy decisions as they relate to the tasks in this Performance Work Statement (PWS). Quick responses are those

that require completion in one to seven days, or as specified in a work assignment. EPA will review the results of all contractor analyses, and make a final determination with regard to program objectives and policy decisions.

2.6 The contractor shall comply with the requirements for studies and rulemaking records contained in authorities such as the Administrative Procedures Act, the Paperwork Reduction Act, the Clean Water Act, OMB Circular A-130 for management of Federal Information Resources, and the Federal Rules of Appellate Procedure (Rules 16 and 17, 28 U.S.C. Appendix).

2.7 The contractor shall perform the specific tasks in the PWS in accordance with the appropriate EPA risk assessment guidance and science policy guidance (e.g., guidance on the development of a human health criteria document), as indicated in a work assignment.

3.0 SPECIFIC TASKS

3.1 Preparation of Human Health Documents

3.1.1 The contractor shall prepare summaries of peer-reviewed literature on infectivity, and clinical and epidemiological endpoints, as specified in a work assignment. Each summary shall discuss the test protocol (e.g., endpoints measured; test species; the number, sex, and species of the control group and dosing group; the method, frequency, and duration of dosing), and shall evaluate the test protocol. Similarly, for epidemiological studies, the contractor shall evaluate the protocol, type of study (e.g., case-controlled, community, prospective, or retro prospective), analyses, and conclusions according to criteria as specified as appropriate by the WAM or CO.

3.1.2 The contractor shall prepare screening analyses that display and compare all available data for a microbial pollutant, and build on the summaries in subsection 3.1.1. If required by the work assignment, these analyses shall be presented as electronic data bases.

The contractor shall be able to develop figures, tables or other graphics to display the array of available data for a microbial pollutant building on the summaries in subsection 3.1.1. The requested data arrays may be used to assist in risk communication, facilitate the dose-response assessment and/or improve the transparency of health effects support documents.

The contractor shall collect data, prepare screening analyses and participate in the development of screening methodologies for microbial contaminants that will be useful in the development of future Critical Contaminant Lists (CCLs), prioritizing resources, and in identifying emerging contaminants.

3.1.3 The contractor shall be familiar with Federal and private exposure data bases and obtain them as needed for use in developing assessments. The contractor shall document the methodology, assumptions, and rationales used in the analyses. EPA will make the final decision concerning any recommended finding based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.1.4 The contractor shall prepare, evaluate, and revise exposure and health effects documents. These documents provide information on the criteria that protect human health from exposure to a microorganism in water media. The contractor shall document the methodology, assumptions, and rationales used for this task. EPA will make the final decision concerning any recommended health effects document based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor

provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion

A health effects document for a microorganism shall address, as specified in a work assignment: (1) physical and biological properties of the microorganism; (2) occurrence and environmental fate and transport; (3) infectivity; (4) human exposure to the microorganism; (5) health effects for animals; (6) health effects for humans; (7) mechanisms of infectivity; (8) magnitude of infectious disease effects; (9) a summary of the results of health effects documents prepared by other Federal agencies; and (10) any other areas set forth in the work assignment.

During the development of a health effects document, the contractor shall conduct literature reviews to augment the file of references provided by the EPA PO/WAM with other references.

3.1.5 The contractor shall prepare, evaluate, and revise health advisories for microorganisms. A health advisory provides information that public health officials use to help determine control priorities for pollutants in water as well as providing general information for the public. The contractor shall document the methodology, assumptions, and rationale used to prepare, evaluate, and revise a health advisory. EPA will make the final decision concerning any recommended health advisory based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

A health advisory for a microorganism shall address: (1) general information and properties of the microorganism; (2) occurrence and environmental fate and transport; (3) infectivity; (4) health effects in animals and humans; (5) treatability; (6) magnitude of infectious disease effects; and (7) any other areas set forth in the work assignment.

During the development of a health advisory, the contractor shall conduct literature reviews to augment the file of references provided by the EPA PO/WAM with other references.

3.1.6 The contractor shall provide technical support for the preparation, evaluation, and revision of hazard, exposure, or risk assessment/characterization techniques or methodologies for human health protection. This includes, among other things, providing technical support during the development of methodologies used to develop human health criteria for various water media. The contractor shall document the methodology, assumptions, and rationale used for this task. EPA will make the final decision concerning any recommended technique or methodology based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.1.7 The contractor shall provide on a rapid response basis (as defined in 2.6) analyses of human health risk assessment guidelines for microorganisms, results of human health risk assessments, and treatment technology practices and procedures. This includes, among other things, analysis of the impact of criteria on sensitive populations, and analyses of dose response and infectivity data and exposure data.

3.1.8 The contractor shall prepare, evaluate, and revise technical guidance documents and position papers for microorganisms. These documents provide information on the principles for criteria development (e.g., minimum data requirements and exposure assumptions). The contractor shall document the methodology, assumptions, and rationale used for this task. EPA will make the final decision concerning any recommended technical guidance document based on

its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.1.9 The contractor shall evaluate "raw" data generated from an infectivity or epidemiology study. The raw data will be provided by the EPA PO/WAM. The evaluation shall include a complete description of the protocol used to gather the data; analyses of effects observed, including tabulation of all observations; evaluation of biological significance of endpoints according to EPA published guidelines or other technical documents; statistical analyses of the significance of observations; and conclusions as to existence of exposure-related effects and their implications for human health.

3.1.10 The contractor shall conduct appropriate statistical analyses of infectivity data, or epidemiological data, or exposure data, as specified in a work assignment. These analyses shall be completed in accordance with EPA published guidance or other technical documents.

3.1.11 The contractor shall provide analyses of food and water consumption patterns and associated exposure to infectious agents through foods for the U.S. population. These analyses shall include frequency and amount of specific foods consumed by sex, age, and geographical locations. Data to be analyzed shall include data from Federal data collection efforts, State collection efforts, and special studies. Similarly, the contractor shall provide analyses of exposure data from the Center for Disease Control National Health and Nutrition Examination Survey data base and the EPA National Human Exposure Assessment Survey data base, water quality data from U.S. Geological Survey and morbidity and mortality data on food and waterborne illnesses from available databases and other sources as deemed appropriate.

3.1.12 All of the above tasks and deliverables shall be completed in accordance with EPA published guidelines where available.

3.2 Sewage Sludge

3.2.1 The contractor shall provide technical support during the preparation, evaluation, and revision of procedures for selecting microbial pollutants-of-concern in sewage sludge that is used or disposed of, and shall provide technical support during the evaluation of those pollutants. The contractor shall document the methodology, assumptions, and rationale used for conducting this task. EPA will make the final decision concerning any recommended procedures to be used to select pollutants-of-concern and the evaluation of those pollutants based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion

3.2.2 The contractor shall conduct exposure pathway risk assessments for microbial pollutants in sewage sludge applied to the land, placed on a surface disposal site, or fired in a sewage sludge incinerator. The pathways evaluated for each use or disposal practice shall be the pathways evaluated for each use or disposal practice when the Standards for the Use or Disposal of Sewage Sludge (40 CFR Part 503) were developed, as well as other pathways specified in a work assignment. Results of these risk assessments will be used by EPA to develop limits for pollutants in sewage sludge.

3.2.3 The contractor shall provide technical support during the development of the rationales for the technology-based requirements in a sewage sludge use or disposal standard for pathogens and vector attraction reduction. The contractor shall document the methodology, assumptions, and rationales for this task (e.g.,

the rationale for the 38 percent volatile solids reduction requirement for vector attraction reduction). EPA will make the final decision concerning any recommended operational standard for pathogens and vector attraction reduction based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion.

3.2.4 The contractor shall prepare, evaluate, and revise technical support documents for a standard for the use or disposal of sewage sludge. These documents contain the rationales for the requirements (i.e., general requirements; pollutant limits; management practices; operational standards; and frequency of monitoring, record keeping, and reporting requirements) in a sewage sludge use or disposal standard (see 40 CFR Part 503). The contractor shall document the methodology, assumptions, and rationale used for this task. EPA will make the final decision concerning any recommended technical support document based on its consideration of the appropriate technical information and Agency policy. Regardless of what types of findings the contractor provides, the Agency will determine if the appropriate technical information and Agency policy have been considered, and come to some conclusion

3.3 Statistics Support

3.3.1 The contractor shall have statistical analyses capabilities to perform analyses of environmental data for microbial pollutants to derive descriptive or interpretative statistics.

3.3.2 The contractor shall conduct laboratory/field studies to support the development of water quality criteria, sewage sludge pollutant limits, and other program requirements, as specified in a work assignment.

3.3.3 The contractor shall perform statistical analyses of data from sampling to derive descriptive or interpretive statistics.

3.4 Administrative Record Support

The contractor shall provide data and documentation to be used by EPA in the analysis of technical issues and options for proposed and final regulations, as specified in a work assignment. Deliverables under this task include data summaries, technical reports, option papers, issue papers, and public and confidential records and files. The contractor shall describe and document the data gathering activities; display, characterize, and interpret the data and information collected; obtain copies of any references used; and describe all methodologies used. Written reports and corresponding records and files shall be prepared and organized, indexed, and cross-referenced in an administrative record for a proposed or final regulation so that the analyses and conclusions can be reproduced based on the information in the administrative record for a proposed or final regulation.

3.5 Rule making support

The contractor shall prepare Federal Register notices of EPA criteria and other regulatory documents and will index and summarize public comments on proposed regulations. Using information provided by EPA (i.e., typically public comments submitted in response to a proposed regulation and information collection requests), the contractor shall prepare an index of issues in the information provided by EPA, and cross reference those issues to the public comments. For technical issues assigned by the EPA PO/WAM, the contractor shall, based on knowledge of the appropriate rule making, prepare draft technical responses to the issues in the public comments including all relevant citations to the administrative record. EPA will review the draft technical responses, and prepare the final responses to the comments.

3.6 Preparation of outreach materials

3.6.1 The contractor shall develop outreach materials in support of the tasks in this PWS. These materials include brochures, presentation boards, slide shows, fact sheets, pamphlets, posters, videos, INTERNET layouts, and models. The materials shall be developed for use in media events (e.g., press releases). In addition, the contractor shall provide materials for distribution at presentations. All materials shall be provided in accordance with the limitations set for in the Section H clause titled "PRINTING (EPAAR 1552.208-70)." The contractor shall provide a draft of all materials for approval by the EPA PO/WAM, and shall prepare the final materials based on the EPA PO's/WAM's comments on the draft materials. For print products, the contractor shall provide a camera-ready copy or digital equivalent, and a disk copy in a disk format that enables the material to be loaded onto the INTERNET. This task shall be done only in direct support of the technical requirements in this PWS.

3.6.2 The contractor shall provide, when included in a work assignment, a complete and accurate translation of foreign language articles cited in a criteria document, a health advisory, or a technical guidance document. Translations shall be performed by experienced scientific translators well-versed in statistical, biomedical, microbiological, or epidemiological terminology. The contractor shall insure that there are no terminology or language usage ambiguities that make interpretation and analysis of the findings difficult. No translations shall be made without the written approval of the Project Officer.

3.7 Arranging and conducting workshops

The contractor shall provide support in arranging workshops, conferences, training sessions, and public meetings, and obtaining appropriate individuals to address various issues. Meeting support shall be limited in scope, and shall cover only those meetings required to address the requirements in this PWS. The contractor shall arrange travel only in accordance with the authority and limitations in the Section H clause titled "APPROVAL OF CONTRACTOR TRAVEL" (i.e., the use of contract funds to reimburse travel is strictly limited to logistical support for speakers, scientists, and experts who contribute directly to the requirements of a task in this PWS). The contractor shall support EPA by: (1) providing information for meeting agendas, including typing the agendas; (2) preparing drafts of technical information for use in preparing briefing materials; (3) identifying and inviting speakers and experts to participate in a workshop; (4) arranging for meeting space when Government space is not available; (5) arranging for the appropriate audio-visual equipment; (6) providing advance announcements, registration support, visual aid preparation, logistical support, case study preparation, interactive and role-playing activity development; and (7) preparing the minutes of the meeting, including the meeting results, for approval by the EPA WAM.

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-09

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-11-005	01/01/2011 To 12/31/2012 Base Option Period Number 1	Human Health Assessment: Crypt

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: 2.2, 3.1.6, 3.1.8

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 01/01/2012 To 12/31/2012

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

SFO (Max 2): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 01/01/2011 To 12/31/2012 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee: — LOE:

Cumulative Approved: — Cost/Fee: — LOE:

Work Assignment Manager Name: Shamima Akhter (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 202-566-0000	
	FAX Number:	
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 202-566-1107	
	FAX Number:	
Other Agency Official Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 202-566-1107	
	FAX Number:	
Contracting Official Name: Sandra Stargardt-Licis (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 513-487-2006	
	FAX Number:	

PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-11-005
WORK ASSIGNMENT # 1-09

Title: Human Health Assessment: *Cryptosporidium* and *Giardia* in drinking and ambient water

Work Assignment Manager:
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Alternate WAM:
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Period of Performance: Work Assignment Issuance through December 31, 2012

Contractor SOW: 2.2, 3.1.6, and 3.1.8

Background:
The mission of the U.S. Environmental Protection Agency's (EPA) Office of Water is to protect public health and the environment from adverse effects of pollutants (e.g., toxic chemicals and microbial pathogens) in ambient water, drinking water, wastewater, sewage sludge and sediments. The Safe Drinking Water Act (SDWA) requires the EPA to regulate disease-causing organisms (pathogens) and toxic chemicals in drinking water.

The Safe Drinking Water Act requires the U.S. Environmental Protection Agency (EPA) to publish regulations to control disease-causing organisms (pathogens) and hazardous chemicals in drinking water. One of the regulations published by EPA to control pathogens is known as the Surface Water Treatment Rule (54 FR 27486; June 29, 1989). The purpose of the Long Term 2 (LT2) rule is to reduce illness linked with the contaminant *Cryptosporidim, Giardia* and other disease-causing microorganisms in drinking water. Under the LT 2 Rule *Cryptosporidium* oocysts at or below 0.075 oocysts/liter are considered the maximum value under which conventional drinking water treatment is expected to be capable of providing protection of consumers drinking up to 1.2 liters of water per day. Under the Safe Drinking Water Act's Surface Water Treatment Rule (further referred to as the Rule) *Giardia* cyst Maximum Contaminant Level Goal (MCLG) levels are set at "0" for treated water. In order to meet this requirement, *Giardia* cyst removal by conventional drinking water treatment must be able to reduce cyst levels by 3 orders of magnitude (3 logs) from source waters to insure protection of

consumers drinking up to 2.0 liters of water per day.

Cryptosporidium is a significant concern in drinking water because it contaminates surface waters used as drinking water sources, it is resistant to chlorine and other disinfectants, and it has caused waterborne disease outbreaks. Consuming water with *Cryptosporidium,* a contaminant in drinking water sources, can cause gastrointestinal illness (e.g., diarrhea, vomiting, cramps) and other health risk, which may be severe in people with weakened immune systems (e.g., infants and the elderly) and sometimes fatal in people with severely compromised immune systems (e.g., cancer and AIDS patients).

Cryptosporidium oocysts are common and widespread in ambient water and can persist for months in this environment. The dose that can infect humans is low, and a number of waterborne disease outbreaks caused by this protozoan have occurred in the U.S., most notably in Milwaukee, where an estimated 400,000 people became ill. The healthy people recover within several weeks after becoming ill, but illness may persist and contribute to death in those whose immune systems have been seriously weakened (e.g., AIDS patients). Drugs effective in preventing or controlling this disease are not yet available. The public health concern is worsened by the resistance of *Cryptosporidium* to water disinfection practices by chlorination, although oocysts can be inactivated by ozone and ultraviolet irradiation. However, a well-operated water filtration system is capable of removing at least 99 of 100 *Cryptosporidium* oocysts in the water. Monitoring for this organism in water is currently difficult and expensive.

The purpose of these documents is to serve as informal technical guidance to assist Federal, state, and local officials responsible for protecting public health when emergency spills or contamination situations occur.

Quality Assurance: Tasks 2-3 in this work assignment require the use of secondary data and require a QAPP specific to the activities being conducted. Consistent with the Agency's quality assurance (QA) requirements, the contractor must supplement the quality assurance project plan (QAPP), required under Task 1 of this work assignment, to assure the quality of the secondary data and other data collected to be used under this work assignment. The QAPP must be approved by the EPA before activities using secondary data begin.

The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1 and should follow the attachment titled, QAPP Requirements for projects using secondary data.

Performance Work Statement: The scope of the work in this Performance Work Statement (PWS) will fall under the following task areas:

Task 1: Work plan and monthly progress reports

Task Area 1.1. Work Plan

The contractor shall develop a detail work plan and cost estimate for each task outlined in this work assignment. The plan should contain, but not limited to, work-flowchart,

elaborate schedule (task-wise), staffing plan and qualifications of proposed staff, budget for each task and level of effort (LOE). Prior to the submission of the work plan, the contractor shall consult with the EPA WAM via conference call to mitigate any potential issues that need clarifications. The contractor shall include information on plans to manage work and control contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than $100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs' broken out by the tasks in this WA.

Task Area 1.2. Develop project specific QAPP

Tasks 2-3 in this PWS require the use of secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor must comply with the contract level quality assurance project plan (QAPP) dated March 2012 to assure the quality and analyze of the secondary data and other data collected to be used under this work assignment. The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports.

The work plan shall explain if any additional QA supplemental information will be submitted based on the specific data requirements of the WA. All projects in Tasks 2-3 that involve secondary data must comply with the approved contract level QAPP prior to the commencement of work.

Task 2: Develop Health Assessment document: *Cryptosporidium*

2.1 *Literature search*

In order to develop the document for *Cryptosporidium*, a thorough literature search, retrieval, and characterization of the data base on *Cryptosporidium* need to be conducted. It is noted that EPA WAM will conduct In-house literature search from 2006 until now and will provide full articles to the contractor through CD or electronically. The literatures prior to 2006 are available at the *Cryptosporidium* Risk Assessment document generated by the ICF. The contractor is advised to include those literatures, if needed for the health assessment document.

2.2 *Develop analysis plan and conduct exposure and dose response analysis*

Historical technical data that was used to generate the LT2 will be obtained from the EPA's Water Docket.

The health assessment document shall be comprised of a comprehensive review of published literatures on *Cryptosporidium* providing all relevant information, the general

characteristics of this protozoan, its occurrence in human and animal populations and in water, drinking water exposures, dose response, the health effects associated with *Cryptosporidium* infection are important features of the health assessment and all data of this nature should be captured from both US and foreign data bases. The EPA WAM will provide the *outline for the drinking and ambient water health assessments* to the contractor. The contractor shall evaluate several different permutations of the available feeding study dose response information for various strains and their combination. The contractor shall also estimate dose based upon 1.2 and 2.0 liters of water/day.

The contractor shall coordinate with the EPA WAM in the collection of datasets for exposure and dose response from various sources for the analysis. Collection of datasets will be conducted such that the Office of Management and Budget (OMB) Information Collection Rule (ICR) will not be triggered.

2.3 *Submit draft report of initial findings*

The contractor shall prepare a draft *Cryptosporidium* health assessment document for EPA WAM review. The contractor shall insure that all factors that were applied to the health assessment are stated and are transparent throughout the document. It is EPA's concern that contractor shall include a list of references used for this task. In addition, the contractor shall also include a list of unused references along with clear justification for not using them. The contractor shall coordinate with the EPA WAM as inclusion or exclusion of any references to the draft document.

2.4 *Incorporate EPA comments and additional studies*

The EPA WAM will periodically search diverse data bases for potential new information and will provide to the contractor. The contractor shall incorporate any additional studies into revisions to draft report upon receipt from EPA WAM. It is the goal of the EPA WAM to gather as many examples as possible and available to help inform the policy development process. The contractor shall also incorporate EPA WAM's review comments to the document.

2.5 *Submit revised report*

The contractor shall revise and finalize the health assessment document based upon EPA WAM's review comments.

2.6 *Communication piece*

The contractor shall provide a brief communication (1- 3 pages) which will aid in briefing manager and senior managers. The communication piece shall be written in plain English language for non-technical people and the relevant scientific studies shall be included as an attachment.

2.7 *Response to the Peer Reviewer comments*

Upon receipt of the EPA's external expert peer-review of the Contractor's Final Written Report, the EPA WAM will provide the Contractor with the recommended edits and modifications. The Contractor shall address all recommended peer-review modifications. Changes will be documented in a separate report for the record to describe how the peer-review comments were incorporated into the final report.

2.8 *Incorporate Peer Reviewer comments to the documents*

The contractor shall incorporate all recommended edits and modifications to the documents. The Contractor shall provide the revised final report (and documented changes to the report) to the EPA WAM for review.

2.9 *Submit Final Report*

Upon the EPA WAM's approval, the Contractor shall send the final revised peer-reviewed report in Microsoft Word, version 2003 or higher, to the EPA WAM.

Task 3: Develop Health Assessment document: *Giardia*

3.1 *Literature search*

In order to develop the document for *Giardia*, a thorough literature search, retrieval, and characterization of the data base on *Giardia* need to be conducted. It is noted that EPA WAM will conduct In-house literature search from 2006 until now and will provide full articles to the contractor through CD or electronically. The literatures prior to 2006 are available at the *Giardia* Risk Assessment document generated by the ICF. The contractor is advised to include those literatures, if needed for the health assessment document.

3.2 *Develop analysis plan and conduct exposure and dose response analysis*

Historical technical data that was used to generate the LT2 will be obtained from the EPA's Water Docket.

The health assessment document shall be comprised of a comprehensive review of published literatures on *Giardia* providing all relevant information, the general characteristics of this protozoan, its occurrence in human and animal populations and in water, drinking water exposures, dose response, the health effects associated with *Giardia* infection are important features of the health assessment and all data of this nature should be captured from both US and foreign data bases. The EPA WAM will provide the *outline for the drinking and ambient water health assessments* to the contractor. The contractor shall also estimate dose based upon 1.2 and 2.0 liters of water/day.

The contractor shall coordinate with the EPA WAM in the collection of datasets for exposure and dose response from various sources for the analysis. Collection of datasets

will be conducted such that the Office of Management and Budget (OMB) Information Collection Rule (ICR) will not be triggered.

3.3 *Submit draft report of initial findings*

The contractor shall prepare a draft *Giardia* health assessment document for EPA WAM's review. The contractor shall insure that all factors that were applied to the health assessment are stated and are transparent throughout the document. It is EPA's concern that contractor shall include a list of references used for this task. In addition, the contractor shall also include a list of unused references along with clear justification for not using them. The contractor shall coordinate with the EPA WAM as inclusion or exclusion of any references to the draft document.

3.4 *Incorporate EPA comments and additional studies*

The EPA WAM will periodically search diverse data bases for potential new information and will provide to the contractor. The contractor shall incorporate any additional studies into revisions to draft report upon receipt from EPA WAM. It is the goal of the EPA WAM to gather as many examples as possible and available to help inform the policy development process. The contractor shall also incorporate EPA WAM's review comments to the document.

3.5 *Submit revised report*

The contractor shall revise and finalize the health assessment document based upon EPA WAM's review comments.

3.6 *Communication piece*

The contractor shall provide a brief communication (1- 3 pages) which will aid in briefing manager and senior managers. The communication piece shall be written in plain English language for non-technical people and the relevant scientific studies shall be included as an attachment.

3.7 *Response to the Peer Reviewer comments*

Upon receipt of the EPA's external expert peer-review of the Contractor's Final Written Report, the EPA WAM will provide the Contractor with the recommended edits and modifications. The Contractor shall address all recommended peer-review modifications. Changes will be documented in a separate report for the record to describe how the peer-review comments were incorporated into the final report.

3.8 *Incorporate Peer Reviewer comments to the documents*

The contractor shall incorporate all recommended edits and modifications to the documents. The Contractor shall provide the revised final report (and documented changes to the report) to the EPA WAM for review.

3.9 *Submit Final Report*

Upon the EPA WAM's approval, the Contractor shall send the final revised peer-reviewed report in Microsoft Word, version 2003 or higher, to the EPA WAM.

Period of Performance/Milestones: It is the Contractor's responsibility to coordinate with EPA WAM while conducting these tasks.

Task	Milestone	Date due
1	1.1 Work Plan	Within 2 weeks of receipt of WA
1	1.2 QAPP	Within 2 weeks of receipt of WA
1	Kick-off meeting with EPA WAM	1 week after WP approval
2.1	EPA will provide literatures and outline for the Health Assessment document	1week after WP approval
2.2	Develop analysis plan and conduct exposure and dose response analysis	3 Weeks after WP approval
2.3	Submit draft report of initial findings	1 month after WP approval
2.4	Incorporate EPA comments and additional studies, if identified	1.5 months after WP approval
2.5	Submit revised report	2 months after WP approval
2.6	Communication Piece	TBD
2.7	Response to the Peer Reviewer comments	TBD
2.8	Incorporate Peer Reviewer comments	TBD
2.9	Submit final report	TBD
3.1	EPA will provide literatures and outline for the Health Assessment document	1week after WP approval
3.2	Develop analysis plan and conduct exposure and dose response analysis	3 Weeks after WP approval
3.3	Submit draft report of initial findings	1 month after WP approval
3.4	Incorporate EPA comments and additional studies, if identified	1.5 months after WP approval
3.5	Submit revised report	2 months after WP approval
3.6	Communication Piece	TBD
3.7	Response to the Peer Reviewer comments	TBD
3.8	Incorporate Peer Reviewer comments	TBD
3.9	Submit final report	TBD

Knowledge and Skills Required: The contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this PWS. The contractor shall be an accomplished microbial risk assessor with experience in environmental media, especially water. The contractor shall have knowledge and experience with the *Cryptosporidium and Giardia spp.* protozoa in water and water/wastewater treatment/disinfection effectiveness. The contractor shall be experienced in evaluation of data bases, statistics, and modeling regarding human exposure, dose response and health effects for application in microbial risk assessments.

General Requirements of the Work Assignment and Schedule:

Due Dates: The Contractor shall provide due dates that are mutually acceptable with the EPA WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.

Delays: The Contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.

Draft Documents: The Contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. EPA WAM will provide comments on draft submissions prior to submission of final documents.

Final Documents: The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM.

Final Documents: The Contractor shall revise and incorporate all EPA's comments and submit final documents both electronically and in hardcopy (Microsoft version 2003 or higher) to EPA WAM. The Agency may decide to publish the report on the web. If this occurs, the report will need to be 508 compliant and the COR will provide appropriate technical direction.

Final Peer Reviewed Document: Upon receipt of the EPA's external expert peer-review of the Contractor's Final Written Report, the EPA WAM will provide the Contractor with the recommended edits and modifications. The Contractor shall address all recommended peer-review modifications. Changes will be documented in a separate report for the record to describe how the peer-review comments were incorporated into the final report. The Contractor shall provide the revised final report (and documented changes to the report) to the EPA WAM for review. Upon the EPA WAM's approval, the Contractor shall send the final revised peer-reviewed report in Microsoft Word, version 2003 or higher, to the EPA WAM.

Attachment 1
QAPP REQUIREMENTS FOR PROJECTS USING SECONDARY DATA

A secondary data project involves the gathering and/or use of existing environmental data for purposes other than those for which they were originally collected. These secondary data may be obtained from many sources, including literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. For these projects, a QAPP shall be prepared to include the requirements identified below. If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the secondary data. The following requirements should be addressed as applicable.

SECTION 1.0, PROJECT OBJECTIVES, ORGANIZATION, AND RESPONSIBILITIES

1.1 The purpose of study shall be clearly stated.
1.2 Project objectives shall be clearly stated.

1.3 The secondary data needed to satisfy the project objectives shall be identified. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable, shall be specified.

1.4 The planned approach for evaluating project objectives, including formulas, units, definitions of terms, and statistical analysis, if applicable, shall be included.

1.5 Responsibilities of all project participants shall be identified, meaning that key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

SECTION 2.0, SOURCES OF SECONDARY DATA

2.1 The source(s) of the secondary data must be specified.
2.2 The rationale for selecting the source(s) identified shall be discussed.
2.3 The sources of the secondary data will be identified in any project deliverable.

SECTION 3.0, QUALITY OF SECONDARY DATA

3.1 Quality requirements of the secondary data must be specified. These requirements must be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if applicable. (If appropriate, a related QAPP containing this information can be referenced.)

3.2 The procedures for determining the quality of the secondary data shall be described.

3.3 If no quality requirements exist, this shall be stated in the QAPP. If no quality requirements exist or if the quality of the secondary data will not be evaluated by EPA, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the secondary data has not been evaluated by EPA for this specific application. The wording for the disclaimer shall be defined.

SECTION 4.0, DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION

4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.

4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.

4.3 The expected product document that will be prepared shall be specified (*e.g.*, journal article, final report, *etc.*).

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-10

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-11-005	01/01/2011 To 12/31/2012 Base Option Period Number 1	Secondary Contact WQS-Pathogen

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: 3.1,3.3,3.4

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 01/01/2012 To 12/31/2012

Comments:

[ ] Superfund — Accounting and Appropriations Data — [X] Non-Superfund

SFO (Max 2): [ ]

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 01/01/2011 To 12/31/2012 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee: — LOE:

Cumulative Approved: — Cost/Fee: — LOE:

Work Assignment Manager Name: Gary Russo (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 202-566-1335	
	FAX Number:	
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 202-566-1107	
	FAX Number:	
Other Agency Official Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 202-566-1107	
	FAX Number:	
Contracting Official Name: Sandra Stargardt-Licis (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 513-487-2006	
	FAX Number:	

PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-11-005
WORK ASSIGNMENT #1-10

Title: Secondary Contact Water Quality Standards for Pathogens

Work Assignment Manager: Gary Russo (Mail Code 4305T)
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Alternate WAM: Sharon Nappier (Mail Code 4304T)
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Period of Performance: Work assignment issuance through October 31, 2012

Contractor SOW: 3.1, 3.3, and 3.4

CBI: No confidential business information will be needed for this work assignment.

Background:

An effort is currently underway to revise EPA's bacteriological water quality criteria under section 304(a) of the Clean Water Act (CWA). Both the current and proposed revised criteria primarily address water quality standards for "primary contact" recreational uses and do not significantly address "secondary contact" recreational uses. Primary contact recreation is typically defined as water-based recreational activities that could be expected to result in the ingestion of or immersion in water such as swimming, water skiing, or surfing. Secondary contact recreation is typically defined as water-based recreational activities where contact with the water is either incidental or accidental, and the probability of ingesting appreciable quantities of water is minimal.

Current EPA policy allows States, tribes and territories to adopt bacteriological criteria for secondary contact uses that are less stringent than criteria for primary contact uses.

The justification for less stringent secondary contact criteria is based on the assumption that secondary contact activities are associated with exposure to fewer pathogenic organisms. It is believed that a higher concentration of pathogens in water is counterbalanced by a lower potential exposure to those pathogens, resulting in the same risk of illness associated with primary recreational activities. However, the potential for pathogen exposure during different recreational activities is not well characterized, and there is currently no scientific consensus on whether or not they are in fact associated with different risks of illness (differential risk).

Although there is a body of scientific literature addressing the risk of illness associated with various water-based recreational activities, the relationships between different activities, water quality, and health risks are not well understood. The wide ranges of existing studies often have ambiguous results or support conflicting conclusions. Such ambiguity and/or disagreement may be due to a variety of reasons, including differences in the questions being addressed, differences, biases and/or flaws in the way the studies were design or conducted, differences in interpretation of the study results, or simply due to chance.

The purpose of this Performance Work Statement (PWS) is to examine the evidence for or against differential risk by conducting a systematic review. A systematic review is a specific type of literature review that focuses on a specific research question and tries to identify, appraise, select and synthesize all high quality research evidence relevant to that question. The overall goal of a systematic review is to provide an objective and transparent synthesis of research results that minimizes bias. The systematic review from this PWS will provide an up-to-date, state-of-the-art evaluation of the current scientific knowledge of the health risks associated with different water-based recreational activities in water contaminated by fecal material. The results and conclusions of the systematic review will be used to inform EPA policies and decisions associated with recreational water quality standards for the protection of public health.

Performance Work Statement (PWS):

The scope of work in this PWS will fall under the following tasks:

Task 1 – Kickoff meeting, work plan, quality assurance, and monthly progress reports

Task Area 1.1. Introductory ("Kick-Off") Conference Call

The contractor shall participate in a kickoff meeting with the EPA WAM and EPA staff designated by the EPA WAM via conference call within five (5) days of receipt of the work assignment (WA). The purpose of the kickoff meeting is to discuss and clarify expectations, answer any questions, identify and resolve any potential problems, and to discuss the contractor's proposed schedule to meet task

area deadlines. The contractor shall provide notes from the Kickoff meeting to the EPA WAM within two (2) business days of the meeting.

- Deliverable – Notes from conference call.
- Deadline – fifteen (15) calendar days following the receipt of the WA.

Task Area 1.2. Work plan

The contractor shall develop a work plan to address all tasks in the performance work statement (PWS). The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If one or more subcontractor(s) are proposed and they are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. The number and professional level of hours charged and total dollars for each task will be provided. Other costs greater than $100.00 shall be itemized.

- Deliverable – Work plan.
- Deadline – fifteen (15) calendar days following introductory meeting.

Task Area 1.3. Quality assurance

Tasks 2 and 3 in this work assignment require the use of secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor shall develop a quality assurance project plan (QAPP) to assure the quality of the secondary data or any other types of data used under this PWS. The QAPP must be approved by the EPA WAM before activities using secondary data begin.

The project specific quality assurance requirements shall be addressed in the work plan and monthly progress reports and should follow Attachment 1 entitled: "QAPP requirements for projects using secondary data." The work plan shall explain when the QAPP will be submitted on the basis of the specific data requirements for the work assignment. All projects that involve secondary data must have an approved QAPP before work begins. See Attachment 1.

In addition to the developing a project-specific QAPP, the contractor shall specify the quality assurance (QA) and quality control (QC) procedures that will be implemented in the systematic review within the systematic review protocol to be developed as specified in Task Area 2.2. The systematic review protocol shall include all QA/QC procedures that will be followed when subsequently performing the systematic review as described in Task Area 2.4.

Upon completion of the systematic review, the contractor shall complete the EPA Office of Water Information Quality Guidelines checklist and supporting narrative. See Attachment 2.

- Deliverable – Project-specific QAPP.
- Deadline – seven (7) calendar days following approval of the Work Plan.
- Deliverable – Completed Information Quality Guidelines checklist
- Deadline – seven (7) calendar days following technical direction from the EPA WAM.

Task Area 1.4. Monthly Progress Reports

The contractor shall provide progress and financial reports to the EPA WAM each month. The contractor shall also provide any information related to the execution of this PWS when ever requested by the EPA WAM at any time. The progress report shall indicate, in a separate QA/QC section, whether QA/QC issues have been identified and how they will be resolved. If significant QA/QC issues are encountered, the contractor shall contact the EPA WAM immediately to discuss the issue. If work ceases because of QA/QC issues, the contractor shall not resume work until receiving written approval from the EPA WAM. Monthly financial reports shall at minimum include a table with the invoice LOE and costs for each task and task area in this PWS.

Task 2 – Develop a systematic review of the scientific evidence related to differential risk of illness with different water-based recreational activities.

Task Area 2.1. Summarize methods, procedures, and approaches for conducting systematic reviews.

Before beginning a systematic review, a review protocol must be developed. The purpose of the review protocol is to clearly describe the methods, procedures, and approaches that will be used to perform the systematic review before the review is conducted. The contractor shall develop a review protocol as described in Task Area 2.2 below. Before the contractor begins work on the review protocol itself, however, the contractor shall develop a short, concise report that summarizes established methods, procedures, and approaches for conducting systematic reviews. In addition, the contractor shall also specify in the Methods Report which methods, procedures and approaches are expected to be utilized in the systematic review protocol that will be developed and the reasons why.

The contractor shall attempt to use established, state-of-the-art systematic review methods, procedures, and approaches in the systematic review protocol whenever possible and appropriate. If the contractor plans to deviate from established,

state-of-the-art methods, procedures or approaches, the contractor shall identify those methods, procedures, and approaches, describe how and why the protocol will deviate from them, and identify the potential impacts on the goals and objectives of the systematic review.

The contractor shall work closely with the EPA WAM during development of the Methods Report and be available for telephone and conference calls as needed. The final Methods Report shall be well written, organized thoughtfully, concise, grammatically correct, have no spelling errors, and academically rigorous. The contractor shall not begin developing the systematic review protocol itself until the final Methods Report is approved and the contractor receives written instructions by the EPA WAM to do so.

- Deliverable – Systematic review Methods Report.
- Deadline –thirty (30) days after approval of the Work Plan by the EPA WAM.

Task Area 2.2. Develop a systematic review protocol.

The contractor shall develop a systematic review protocol that reflects current state-of-the-art methods and procedures for conducting systematic reviews, and reflects the general plan outlined in the systematic review Methods Report developed in Task Area 2.1. If, after beginning work on the review protocol itself, the contractor believes the review protocol may need to deviate from the planned methods, procedures, or approaches outlined in the Methods Report, the contractor shall identify those methods, procedures, or approaches, describe how and why the protocol should deviate from them, and identify how such a deviation may potentially impact the goals and objectives of the systematic review.

The review protocol shall be developed in close collaboration with the EPA WAM and other EPA staff designated by the EPA WAM. The contractor shall not begin the review itself until the review protocol has been fully developed and approved by the EPA WAM. At a minimum, the review protocol shall address the following key areas:

Scientific questions to be addressed. The review protocol shall clearly describe the scientific question(s) to be addressed by the review, and how the answers to those questions may provide meaningful information to inform EPA decision-making about primary versus secondary contact criteria and designated uses. The review questions shall be developed in close consultation with the EPA WAM, and be stated clearly and precisely in the review protocol. Once the final scientific questions are determined, the sole purpose of the systematic review shall be to

address only those questions. Under no circumstances shall the systematic review deviate from addressing the established scientific questions without written approval from the EPA WAM.

Background. The review protocol shall have a background section that clearly communicates the key contextual factors and conceptual issues relevant to the review questions. It should explain why the review is required and provide the rationale underpinning the inclusion criteria and the focus of the review questions.

Search strategy. The review protocol shall specify the search strategy that will be used to identify relevant studies that could potentially be included in the review. The contractor shall clearly and transparently describe all steps in the search strategy so that the search results can be reliably reproduced. These details include but are not limited to specifying the databases and additional sources that will be searched and the search terms to be used. Provisions for repeating the searches during the review process and details about how the contractor will manage references shall also be specified.

Inclusion criteria. The review protocol shall describe the criteria for selecting studies that will be included in the review. Factors to consider include population, interventions, comparators, outcomes, and study design. To avoid publication bias, the inclusion criteria shall consider all relevant studies regardless of publication status, including but not limited to peer-reviewed journals, reports, book chapters, conference abstracts, theses, informal reports, and unpublished studies. Studies in any language shall be considered to avoid language bias. If translation of all relevant studies is not feasible, the inclusion criteria shall describe how non-English studies will be addressed in the review.

Study selection. The contractor shall specify in the review protocol the process by which decisions on the selection of studies will be made. Study selection is usually conducted in two stages: an initial screening of titles and abstracts against the inclusion criteria to identify potentially relevant papers, followed by complete screening of papers identified as possibly relevant in the initial screening. The review protocol shall clearly and fully describe the processes that will be used for both stages of study selection. The contractor shall also specify the number of researchers who will screen titles and abstracts and then full papers, and the method for resolving disagreements about study eligibility.

Data abstraction. To the extent possible, the review protocol shall describe the information that will be extracted from studies identified for inclusion in the review. The review protocol shall clearly state the procedures expected to be used for data extraction, including the number of researchers who will extract the data and how discrepancies will be resolved. The protocol shall also specify whether authors of primary studies will be contacted to provide missing or additional data.

If non-English language papers are to be included, translation arrangements will also be specified.

Quality assessment. The protocol shall provide details of the method of study appraisal to be used, including examples of the specific quality criteria. The review protocol shall specify the process for appraising study quality, and the process for weighting studies on the basis of their appraised quality. The review protocol shall also specify how disagreements among study appraisers will be resolved.

Data Synthesis. To the extent possible, the protocol shall specify the strategy for data synthesis. The protocol shall describe the conditions necessary to perform a meta-analysis and how the meta-analysis will be conducted. To the extent possible, the protocol shall describe how heterogeneity will be explored and quantified, and whether a fixed or random-effects model or both will be used and why. The protocol shall also specify the outcomes of interest and what effect measures will be used. The protocol shall describe any planned subgroup or sensitivity analyses or investigation of publication bias and the reasons why. An approach to conducting narrative synthesis shall also be developed and described. If any of the above analyses are not planned, justification for not performing them shall be provided.

QA/QC. The contractor shall incorporate into the review protocol all QA/QC procedures that will be followed while conducting the systematic review. These QA/QC procedures shall be specified within the relevant areas of the review protocol so that the QA/QC procedures to be followed are readily apparent during performance of each stage of the systematic review process.

- Deliverable – Systematic review protocol.
- Deadline – sixty (60) days after the EPA WAM approves the Methods Report. The WAM will provide the contractor with written instructions to begin work on the review protocol.

Task Area 2.3. Revise the review protocol in response to possible peer review comments.

After the systematic review protocol has been approved by the EPA WAM, the EPA WAM may decide that a peer review of the protocol by independent experts outside the EPA is needed. Should the EPA WAM decide that an external peer review is necessary, the contractor shall provide assistance and advice in developing the charge for the peer review and in interpreting the peer review comments. Should the EPA WAM decide that the review protocol needs to be revised in response to an external peer review, the contractor shall revise the

review protocol in accordance with the technical direction provided by the EPA WAM. The contractor shall adhere to the same standards of quality as when initially developing the review protocol as specified in Task Area 2.2 Revisions shall be performed in close collaboration with the EPA WAM and other EPA staff designated by the EPA WAM. The contractor shall not begin the review itself until the review protocol has been finalized and the contractor receives written instructions to do so by the EPA WAM.

- Deliverable – Revised review protocol.
- Deadline – thirty (30) days after receiving peer review comments.

Task Area 2.4. Conduct the systematic review.

Upon completion of the final review protocol and receiving written instructions by the EPA WAM, the contractor shall conduct the systematic review as specified in the review protocol. During the screening phase, the contractor shall inform the EPA WAM of the results of initial screening process before beginning full screening of potentially relevant papers. When performing the systematic review, the contractor shall strictly adhere to the review protocol and shall not deviate from it without explicit written permission from the EPA WAM.

Although one objective of the systematic review is to strictly adhere to the review protocol once finalized, modification of the finalized review protocol may be appropriate in some circumstances such as when a clearer understanding of the review question(s) becomes apparent, or when initial screening of papers using the specified eligibility criteria results in too few or too many papers. If, after initial consideration of the studies being reviewed, it becomes apparent that a change in direction may be required, the contractor shall immediately cease review activities and notify the EPA WAM. If the EPA WAM determines that protocol modifications are needed, the contractor shall modify the protocol in consultation with the EPA WAM. The contractor shall not resume review activities until the final modified review protocol is reviewed and approved by the EPA WAM and the contractor receives written instructions to resume review activities. Protocol modifications shall be clearly and fully documented in a protocol addendum and in the final report of the review findings. This documentation shall include a clear description of the differences between the initial and amended protocol, and the implications of the modification on the review findings. **Under no circumstances shall the protocol be modified or the review altered because of awareness of the results of individual studies.**

Throughout the review process, the contractor shall provide progress reports to

the EPA WAM. The contractor shall also provide electronic copies of all documents that were screened during the study selection process or used in the systematic review. A database of complete document citations along with the file name of the electronic copy shall also be provided to the EPA WAM as an Endnote database or another electronic format that can easily be imported into Endnote.

At the conclusion of the systematic review, the contractor shall provide a brief report outlining the results of the review. The report shall be well written, organized thoughtfully, concise, grammatically correct, have no spelling errors, academically rigorous, contain high quality tables and figures if needed, and formatted so that it can serve as the foundation for developing a manuscript to be submitted for publication in a high-quality peer-reviewed journal.

- Deliverable – Report on review results.
- Deadline – ninety (90) days after receiving instructions from the EPA WAM to begin the systematic review.

Task Area 2.5. Develop one or more manuscripts for publication of the systematic review.

At the conclusion of the systematic review, the contractor shall develop one or more manuscripts for publication of the systematic review. The manuscript(s) shall be developed in close consultation with the EPA WAM with the goal of publishing the systematic review in a high quality, high impact, peer-reviewed journal. The manuscript(s) shall be organized thoughtfully, written concisely, grammatically correct, academically rigorous, contain high quality tables and figures when appropriate, and formatted for the journal being targeted. The manuscript(s) shall be developed in a way that allows reformatting for submission to other journals if the need arises. The contractor shall revise the manuscript(s) as instructed by the EPA WAM in response to reviewer comments, and develop written responses to reviewer comments for submission to the journal editor. The contractor shall conform to the same standards of quality when revising the manuscript(s) as specified above for initially developing the manuscript(s). The contractor shall also prepare the Information Quality Guidelines Checklist necessary for products that EPA disseminates to the public under EPA's Information Quality Guidelines.

- Deliverable – Draft manuscript.
- Deadline – thirty (30) days after receiving instructions from the EPA WAM to begin writing manuscript.

Task Area 3 - General Project Support

Task Area 3.1. Prepare briefing materials and other supporting documents pertaining to the systematic review.

Briefing materials and other supporting documents will be needed during the systematic review development process and after the review is published. The contractor shall aid in the development of any materials or presentations for these purposes. This may include but is not limited to preparing interim project updates and other materials for internal and external audiences as requested by the EPA WAM, briefing documents, PowerPoint presentations, and other supporting documents as needed. The contractor may be requested by the EPA WAM to participate in and/or conduct briefings or participate in seminars or talks related to the systematic review.

- Deliverable – Requested materials and supporting documents.
- Deadline – As agreed upon by the WAM and contractor

Task Area 3.2. Support options development and analyses for potential changes to EPA policies related to bacteriological water quality standards.

As the results and conclusions of the systematic review become clear, the EPA may want to consider alternative policies related to bacteriological water quality standards. The contractor shall aid in the development of potential alternative policy options. These activities may include but are not limited to performing additional research and analysis of existing scientific data and information, analysis of the potential public health outcomes resulting from policy modifications, and the analysis of water quality standard implementation implications associated with the adoption of alternative bacteriological water quality standards. The contractor may be requested to participate in and/or conduct briefings or other presentations related to this work.

- Deliverable – Requested materials.
- Deadline – As agreed upon by the WAM and contractor
-

Travel:

Travel may be needed as deemed necessary by the EPA WAM. No contractor travel outside of the Washington, D.C. metro area is required.

Conferences:

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the EPA PO.

Knowledge and Skills Required:

The contractor shall have the necessary scientific knowledge and expertise to develop the aforementioned materials in this PWS that are high quality and use state-of-the-art methods. Specifically, the contractor shall have experience designing, performing, and publishing primary scientific research evaluating the health effects of environmental pollution, as well as experience designing, performing, and publishing systematic- and meta-analyses of such studies. The contractor shall have expertise in epidemiological studies that evaluate microbiological water pollution using fecal indicator organisms. The contractor shall be proficient in advanced state-of-the-art statistical methods typically used to analyze epidemiological studies and perform meta-analyses. The contractor should also be competent in analytical methods used to monitor microbial water pollution (including molecular techniques), the determination of human exposure to environmental contaminant sources, and disease endpoints related to microbial exposure through contact with water.

General Requirements of the Work Assignment and Schedule:

Due Dates

The contractor shall mutually acceptable due dates with EPA WAM. The contractor shall notify the EPA WAM in advance, if a due date will not be met and negotiate a mutually acceptable revised due date.

Delays

The contractor shall provide sufficient qualified man-power to ensure there are no avoidable delays. If a delay outside the control of the contractor is unavoidable, the contractor shall immediately notify the EPA WAM and negotiate a mutually acceptable revised schedule.

Draft Documents

The contractor shall submit draft or interim work products requested by the EPA WAM. Draft or interim work products shall be prepared in an electronic format compatible with

Microsoft Office 2007 or Endnote X. The EPA WAM will provide the contractor with comments on draft work products in electronic format. Work products shall be deemed draft until designated as final by the EPA WAM.

Final Documents

The contractor shall submit final documents electronically to the EPA WAM.

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-11

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-11-005	01/01/2011 To 12/31/2012 Base Option Period Number 1	Support for Developing Technic

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: 3.1, 3.3, 3.6

Purpose:
- ☒ Work Assignment
- ☐ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 01/01/2012 To 12/31/2012

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 01/01/2011 To 12/31/2012 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee: — LOE:

Cumulative Approved: — Cost/Fee: — LOE:

Work Assignment Manager Name: John Ravenscroft (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1101 FAX Number:
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Other Agency Official Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Contracting Official Name: Sandra Stargardt-Licis (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2006 FAX Number:

Performance Work Statement
ICF Contract # EP-C-11-005
Work Assignment #1-11

Title: Support for Developing Technical Support Materials (TSM) for Deriving Site-Specific Water Quality Criteria Based on Alternative Health Relationships

Work Assignment Manager: John Ravenscroft (Mail Code 4304T)
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Alternate WAM: Shamima Akhter (Mail Code 4304T)
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E-mail: akhter.shamima@epa.gov

Period of Performance: Work Assignment Issuance through December 31, 2012

**Note: No CBI data will be needed in the course of this work assignment.

Contractor PWS: 3.1, 3.3, 3.6

Goal: The overall goal of this work assignment is to develop implementation guidance for States and Tribes to use in developing site-specific water quality criteria based on alternative human health associations with water quality measures.

Objectives:

1. Produce a comprehensive report for internal EPA evaluation detailing the framework, process, and scientific foundation that the intended end users of this information (i.e., States, Tribes, and EPA) can utilize in developing and evaluating a site-specific water quality standards package based on an alternative human health relationship with water quality.
2. Respond to EPA and peer review comments on the report covered in Objective 1.
3. Produce a polished report in response to Objective 2 that the Agency can publish on its website
4. Produce communications materials to accompany reports including: a 1 to 2 page nontechnical synopsis, a technical summary document written in non-academic style for a non-scientific audience, a 'questions and answers' (Q&As) document covering areas of

potential inquiry from nontechnical and technical audiences (both internal and external), and others as determined by the EPA WAM via technical direction.

Background: EPA is on track to issue new CWA 304(a) Recreational Water Quality Criteria (RWQC) by December 2012. The science underpinning the new criteria describes human health effects and water quality studies conducted in waters impacted primarily by human sources of fecal contamination. EPA recommended water quality criteria for fecal indicator bacteria based on the epidemiological studies conducted by EPA's Office of Research and Development (ORD). These studies were conducted at a subset of recreational waters impacted by human fecal contamination. While EPA considers these recommended criteria to be scientifically defensible and protective of the use on a national basis, the Agency recognized that certain site-specific conditions exist that would allow alternative, equally protective, criteria to be considered for Water Quality Standards. EPA clarified additional potential approaches to developing site-specific water quality criteria in Section 5 of the draft RWQC published in December 2011. These approaches focused on three main areas: 1) alternative indicators; 2) alternative sources of fecal contamination; and 3) alternative health relationships. This work assignment addresses the alternative health relationship approach.

Generally speaking, the alternative health relationship approach would consist of the development of a site-specific recreational water quality criteria derived from a human health association with water quality that differs from the one EPA has used as the basis for the nationally-applicable 2012 recommendations. EPA has committed to publishing implementation guidance, hereafter termed Technical Support Materials (TSM), for use by States and Tribes who may be interested in pursuing the development of site-specific criteria. This work assignment covers the various aspects needed to develop these TSM, including the collation and development of background and supplemental information needed for the application of this approach in the development of site-specific Water Quality Standards packages to be evaluated by EPA.

Task Knowledge and Skills Required: The Contractor shall have expertise in preparing the materials associated with this work assignment and be knowledgeable with the various fields of discipline discussed, including epidemiology, microbial risk assessment, biostatistics, and environmental microbiology. The Contractor shall be familiar with the different programs under the CWA, use of water quality monitoring, determination of human exposure to environmental contaminant sources, and gastrointestinal (or other) disease endpoints, applications of epidemiological data, and other factors associated with needs in recreational water quality and CWA 304(a) criteria development. The Contractor shall also be able to communicate the study outcomes and recreational outbreak data to a non-technical audience.

Quality Assurance: The tasks in this work assignment (WA) require the use of secondary data/analyses and fall under the scope of the approved contract-level QAPP. Consistent with the Agency's quality assurance (QA) requirements, the contractor must assure the quality and analyses of the secondary data and other data collected to be used under this work assignment.

The Contractor shall discuss with the EPA WAM if any of the specific work assignment tasks are not readily covered under the approved QAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a WA-specific QAPP supplement, which must be approved by the EPA WAM before activities covered by the additional QA language begin under this work assignment.

Task 1: Work plan, monthly progress reports and quality assurance

Task 1.1: Work plan
The contractor shall develop a work plan to address all tasks in this work assignment. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than $100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs delineated by the tasks in this WA. These reports should also indicate an estimate for the next month by task and if any lagging costs are expected. EPA realizes these estimates are just approximate values and is interested in having this information for internal budgeting purposes.

Task 1.2: Information Quality Guidelines
The Contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines and shall complete the Checklist for Influential Information as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. The EPA WAM will provide the checklist to the Contractor. The Contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the Contractor shall document the quality assurance procedures it used in developing the deliverables under this Work Assignment. The Contractor shall provide the memo at the time it delivers the Final Summary Report. The Contractor shall have a teleconference with the EPA WAM to discuss the Guidelines and the Contractor's role in completing the checklist..

Task 2: General Project Support and Development of TSM Considering Alternative Health Relationships

EPA is planning to make available guidance to States for consideration in developing site-specific Water Quality Standards (WQS) packages utilizing alternative human health

associations with water quality measures. Task 2 comprises the different facets of the guidance development project and includes project planning, communication strategies, and document preparation.

Task 2.1. Project planning and management
The Contractor shall conduct project strategic planning in conjunction with the EPA WAM. The purpose of this subtask will be to develop a comprehensive plan that includes all related tasks and deliverables in the context of the Agency timeline for publishing RWQC and implementation guidance. The plan will also describe how each task or subtask will aid EPA in meeting its goals in regards to the publication of technical support materials in support of criteria implementation.

Deliverables under this subtask will include the preparation of a project plan and schedule, including a graphical representation (e.g., Gantt chart) to aid in discussions with management. Project management coordination between the EPA WAM and the Contractor shall occur for the duration of the work assignment. Regular periodic meetings between the EPA WAM and the Contractor shall occur once the workplan has been approved.

Task 2.2.Project communication support
The contractor shall, based on technical direction given by the EPA WAM, provide support in preparing interim project updates and other materials for internal and external audiences. These may include, but are not limited to, short briefing documents and PowerPoint presentations. The Contractor may be requested to participate in briefings and meetings. The Contractor may be requested to prepare reports for communication outside the EPA based on deliverables generated by tasks under this work assignment. The Contractor shall coordinate with the EPA WAM for the proper timing and need for these activities.

Interpretation and meta-analyses of epidemiological evidence are two potential technical areas that will need to be considered in the preparation of the TSM. The Contractor shall anticipate the need to discuss specific topics of a highly technical nature with ORD epidemiologists and also to convey the outcomes of such discussions to a non-technical audience.

Task 2.3: TSM document development
The purpose of this task is to develop a guide for use by States and localities for the purposes of deriving site-specific water quality criteria derived from alternative human health relationships to water quality, including information for evaluating the technical basis for the site-specific criteria. This guide should also provide information for EPA, particularly for Regional personnel who are tasked to evaluate State WQS packages. This document shall discuss a process to help States determine if a water body is eligible for the development of site-specific criteria, what information can be used to provide a line of evidence approach for demonstrating human health relationships with water quality, the differing approaches to establishing human health relationships with water quality, a comparison of site-specific health relationships to those used by EPA as a basis for the nationally recommended water quality criteria, a potential epidemiological and Quantitative Microbial Risk Assessment (QMRA) hybrid approach for

demonstrating human health relationships, how to prepare a site-specific water quality standards package, and other topics as needed to be specified by the EPA WAM (and in consultation with HECD's partners in SHPD). The main goal for this deliverable is to produce guidance for use by States in developing microbial WQS that are scientifically defensible, protective of the recreational designated use, and meet EPA standards for consideration and potential approval.

This document should be clear to a potentially non-technical audience on the state of the science for epidemiology and risk assessment. For example, a good discussion will be needed for comparing results from various epidemiological studies conducted with different study designs. The discussion should include what the differences between the study designs are and what impact they have on the potential interpretation of the results, particularly in terms of comparing study results to EPA's recommendations. This type of discussion will be important for evaluating the scientific defensibility and protection of the designated use for any site-specific criteria derived from alternative study designs. The Contractor shall use examples from the peer reviewed literature, where possible, to highlight this discussion.

The draft deliverable for this task (see table below) will need to be peer reviewed by a 3rd party. The Contractor shall respond to the peer reviewer comments as directed by the EPA WAM via technical direction in preparation of the final deliverable. The final deliverable shall be Section 508 compliant as specified in the US Rehabilitation Act internet-based publications.

This task will require the Contractor to attend meetings with the EPA WAM and other staff at EPA Headquarters during the period of performance for the purposes of project updates, planning and communication.

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA WAM as needed and provided to the Project Officer and Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the PO.

General Requirements of the Work Assignment and Schedule:
Due Dates: The Contractor shall provide due dates that are mutually acceptable with the EPA WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.
Delays: The Contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.
Draft Documents: The Contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. EPA WAM will provide comments on draft submissions prior to submission of final documents.

Final Documents: The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM.
Milestone/Deliverable Table

Task	Task #	Milestones and Due Dates
Task 1: Work plan, monthly progress reports and quality assurance		
Workplan	1.1	Within 15 calendar days of receipt of work assignment
Information Quality Guidelines	1.2	Discuss with EAP WAM within 15 calendar days of receipt of work assignment. IQG checklists due with final deliverable (can be included with QA materials).
Task 2: General Project Support		
Project Planning and Management	2.1	Initial planning meeting to be held within 15 calendar days of receipt of work assignment. Meeting shall update project Gantt chart, goals and objectives statement, and gap analysis due within 2 weeks of initial meeting. Drafts of this deliverable would be expected at the close of the initial meeting. Subsequent meetings to be held roughly every quarter thereafter.
Project Communication Support	2.2	After the workplan approval, throughout the period of performance. Communication materials will be informed by the results and be targeted for different audiences..
Technical Support Materials	2.3	Draft for internal review, 11/15/12 (communication materials included); EPA may have additional comments; 3rd party peer review will take approximately 90 days; Contractor shall coordinate with EPA WAM on the response to comments; Final by 4/30/13 contingent on EPA comments.